

EPA Reg # 2517-174

Kumar, Rita

From: Kumar, Rita
Sent: Thursday, February 04, 2016 11:55 AM
To: Carrie Daniels
Cc: James Messina; Kelly Hoskins (Kelly.Hoskins@perrigo.com)
Subject: Pending application - dog squeeze-on imidacloprid
Attachments: 2517-174-20160203.pdf

Dear Carrie: Please see attached. This action is now complete. Kindly acknowledge receipt.
Regards,
Rita



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

2517-174

Date of Issuance:

2/3/16

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
Expires: 2/3/18

Name of Pesticide Product:

Sergeant's 9.1% Imidacloprid
Squeeze On for Dogs

Name and Address of Registrant (include ZIP Code):

Kelly R. Hoskins
Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Venus Eagle, Product Manager 01
Invertebrate-Vertebrate Branch 3, Registration Division (7505P)

Date:

2/3/16

2. This registration is time-limited and expires 2/3/18.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. The following is a list of information that must be included in the quarterly reports for each incident:
 - EPA Registration Number
 - Product name (brand name)
 - Lot #
 - Where purchased: internet, store, veterinarian
 - Active Ingredient(s)
 - Weight range for product
 - Date on which incident occurred (mm/dd/yyyy)
 - State in which the incident occurred (standard 2 letter abbreviation)
 - Registrant case #
 - Species: dog, cat, other (specify)
 - Breed: (as reported by pet owner)
 - Age: months or years
 - Sex: M, F, or neutered
 - Weight: pounds
 - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
 - Body System: neurological, dermatological, GI, respiratory, ocular, other
 - Major signs noted with separate column for each sign, using standard terminology
 - Time to Onset: (hours, days)
 - Treated by veterinarian: yes or no
 - First time product used: yes or no
 - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
 - Any known precondition
 - EPA Severity Code: death, major, moderate, minor
 - Outcome: died, recovered, still treated, unknown
4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
 - All incidents should be reported including all minor dermal and ocular irritation reports.
 - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.

- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for cats and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

5. You are required to comply with the data requirements described in the DCI and EDSP Orders identified below:
 - a. Imidacloprid GDCI-129099-951
 - b. Imidacloprid EDSP-129099

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

http://www.epa.gov/oppsrrd1/contacts_prd.htm

6. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 2517-174."
7. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is

referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 12/30/2015

If you have any questions, please contact Rita Kumar by phone at (703) 308-8291, or via email at kumar.rita@epa.gov.

Enclosure: Stamped label

Sergeant's[®] Master Label

15 January 2016

Version 15.1

EPA Reg. No. 2517-RTU

Information in [] is optional.

Information in { } is note to reviewer.

Page 1 of 11

FRONT PANEL

Dogs Squeeze On Imidacloprid

[Optional text appears in brackets/parenthesis – the final label may include some or all of the optional text on front, back or side label panels]

Sergeant's[®] 9.1% Imidacloprid Squeeze On for Dogs

{Market Label-the word Dog will be at least 40-75% in height of the largest letter in the primary brand name.}

{Market Label a large clear picture of a dog in the respective weight range will be on the front panel of the label for the product as packaged.}

{One of the following statements will appear on appropriate weight band market label on front panel as required per Agency's pet spot-on mitigation measures:}

For use ONLY on dogs [[&][and] puppies] [weighing] 4 [-][to] 10 lbs. and over 7 weeks [old][of age] {0.4 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 4 [-][to] 10 lbs. and 7 weeks [of age] or older {0.4 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 11 [-][to] 20 lbs. and over 7 weeks [old][of age] {1.0 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 11 [-][to] 20 lbs. and 7 weeks [of age] or older {1.0 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 21 [-][to] 55 lbs. and over 7 weeks [old][of age] {2.5 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 21 [-][to] 55 lbs. and 7 weeks [of age] or older {2.5 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] [more than][over][>] 55 lbs. and over 7 weeks [old][of age] {4.0 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] [more than][over][>] 55 lbs. and 7 weeks [of age] or older {4.0 ml size package}

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] 4 [-][to] 10 lbs. {0.4 ml size package}

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] 4 [-][to] 10 lbs. {0.4 ml size package}

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] 11 [-][to] 20 lbs. {1.0 ml size package}

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] 11 [-][to] 20 lbs. {1.0 ml size package}

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] 21 [-][to] 55 lbs. {2.5 ml size package}

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] 21 [-][to] 55 lbs. {2.5 ml size package}

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] [more than] [over][>] 55 lbs. {4.0 ml size package}

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] [more than] [over][>] 55 lbs. {4.0 ml size package}

ACCEPTED

Feb 03, 2016

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 2517-174

[1.5cm x 1.5cm on final]



Sergeant's[®] Master Label

15 January 2016

Version 15.1

EPA Reg. No. 2517-RTU

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Information in { } is note to reviewer.

Page 2 of 11

ACTIVE INGREDIENT:

Imidacloprid.....9.10%

OTHER INGREDIENTS:90.90%

[TOTAL 100.00%]

KEEP OUT OF REACH OF CHILDREN

WARNING

See [Back][or][Side][Label[s]][Panel[s]] for Additional Precautionary Statements

NET CONTENT: X fl oz [Y – X fl oz applicators]

[0.014 fl oz (0.4 mL) [tubes][vials][applicators][pipettes]]

[0.034 fl oz (1.0 mL) [tubes][vials][applicators][pipettes]]

[0.085 fl oz (2.5 mL) [tubes][vials][applicators][pipettes]]

[0.135 fl oz (4.0 mL) [tubes][vials][applicators][pipettes]]

[ABNs]

[SENTRY[®] Vet for Dogs Imidacloprid]

[SENTRY[®] Vet Advanced Flea for Dogs]

[SENTRY[®] Vet FleaGuard for Dogs]

[SENTRY[®] Vet Vantage for Dogs]

[SENTRY[®] Vet Flea Vantage for Dogs]

[SENTRY[®] Advanced for Dogs Imidacloprid]

[SENTRY[®] Advanced FleaGuard for Dogs]

[SENTRY[®] Advanced Vantage for Dogs]

[SENTRY[®] Advanced Flea Vantage for Dogs]

[SENTRY[®] Advanced VetSpot for Dogs]

[PetArmor[®] Vantage for Dogs]

[PetArmor[®] Advant for Dogs]

[PetArmor[®] FleaGuard for Dogs]

[PetArmor[®] Advanced for Dogs]

[PetArmor[®] Flea Vantage for Dogs]

[PetArmor[®] Adv Flea for Dogs]

[PetArmor[®] Adv.Flea for Dogs]

[PetArmor[®] AdVet for Dogs]

[Begin Optional Active Ingredient Reference Statements]

{Note to Reviewer – the following is an example statement:

Contains imidacloprid, the active ingredient used in Advantage[®] 10 Topical Solution*

*[This product is not manufactured by Bayer Healthcare LLC, the makers of Advantage[®] 10 Topical Solution] [OR] [Advantage[®] 10 Topical Solution is a registered trademark of Bayer Healthcare LLC]}

Sergeant's[®] Master Label

15 January 2016

Version 15.1

EPA Reg. No. 2517-RTU

Information in [] is optional.

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Page 3 of 11

[Brand Name] [This product] contains [imidacloprid], the active ingredient used in

[Advantage[®] 10 Topical Solution] [Advantage[®] for Small Dogs] [Advantage[®] TM 10

(Imidacloprid) Topical Solution]

{OR}

[Advantage[®] 20 Topical Solution] [Advantage[®] for Medium Dogs] [Advantage[®] TM 20

(Imidacloprid) Topical Solution]

{OR}

[Advantage[®] 55 Topical Solution] [Advantage[®] for Large Dogs] [Advantage[®] 55 (Imidacloprid) Topical Solution]

{OR}

[Advantage[®] 100 Topical Solution] [Advantage[®] for Extra Large Dogs] [Advantage[®] 100 (Imidacloprid) Topical Solution].

*

{Note to reviewer: Text for footnote statement one}

[* [Brand Name] [This product] is not manufactured or distributed by Bayer Healthcare LLC, the makers of

[Advantage[®] 10 Topical Solution] [Advantage[®] for Small Dogs] [Advantage[®] TM 10 (Imidacloprid) Topical Solution]

{OR}

[Advantage[®] 20 Topical Solution] [Advantage[®] for Medium Dogs] [Advantage[®] TM 20 (Imidacloprid) Topical Solution]

{OR}

[Advantage[®] 55 Topical Solution] [Advantage[®] for Large Dogs] [Advantage[®] 55 (Imidacloprid) Topical Solution]

{OR}

[Advantage[®] 100 Topical Solution] [Advantage[®] for Extra Large Dogs] [Advantage[®] 100 (Imidacloprid) Topical Solution].]

{Note to reviewer: Text for footnote statement two}

[* [Advantage[®] 10 Topical Solution] [Advantage[®] for Small Dogs] [Advantage[®] TM 10 (Imidacloprid) Topical Solution],

{OR}

[Advantage[®] 20 Topical Solution] [Advantage[®] for Medium Dogs] [Advantage[®] TM 20 (Imidacloprid) Topical Solution],

{OR}

[Advantage[®] 55 Topical Solution] [Advantage[®] for Large Dogs] [Advantage[®] 55 (Imidacloprid) Topical Solution],

{OR}

[Advantage[®] 100 Topical Solution] [Advantage[®] for Extra Large Dogs] [Advantage[®] 100 (Imidacloprid) Topical Solution]

is a registered trademark of Bayer Healthcare LLC.]

[End Optional Active Ingredient Reference Statements]

Sergeant's® Master Label

15 January 2016

Version 15.1

EPA Reg. No. 2517-RTU

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Page 4 of 11

[Fleas]

[Prevents further flea infestation for up to [[four][4] weeks][1 month] with one treatment]

[Prevents further flea infestation for up to [[four][4] weeks][1 month] with one application]

[Brand Name] Prevents flea infestation for [four][4] weeks][1 month]

[Kills fleas within 12 hours [of application] on dogs]

[Kills reinfesting fleas within 2 hours]

[Kills [adult] fleas before they lay eggs]

[[Brand Name][This product] kills fleas and may reduce the incidence of a hypersensitivity skin disorder called flea allergy dermatitis (FAD), which may be caused by the feeding activity of fleas.]

[Use [of Brand Name][of this product] kills fleas and may reduce incidence of flea bite hypersensitivity] [and][or] [flea allergy dermatitis] [FAD]]

[Use [of Brand Name][of this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]

[Monthly treatment [with Brand Name][with this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]

[Monthly treatment [with Brand Name][with this product] kills fleas and may reduce incidence of flea bite hypersensitivity [and][or] [flea allergy dermatitis] [FAD]]

[Apply monthly [for optimal flea control]]

[Apply monthly [to control and prevent fleas]]

[Kills fleas]

[Kills fleas within 12 hours, continues to kill for up to 4 weeks]

[Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation]

[Kills fleas, which may be a source of flea allergy dermatitis in 12 hours]

[Active against fleas]

[Kills fleas on [puppies and] dogs]

[[Brand Name] Offers protection against fleas]

[Flea control for puppies and dogs over 7 weeks [old][of age] and 4 lbs]

[Flea control for puppies and dogs 7 weeks [of age] or older and 4 lbs]

[Kills fleas within 12 hours [and prevents further flea infestations for [a][one] [month] [four weeks]]]

[All Others]

[Apply to [dogs and] puppies over 7 weeks old and 4 lbs]

[Apply to [dogs and] puppies 7 weeks or older and 4 lbs]

[SENTRY®]

[PetArmor®]

[[Sergeant's] Caring For Your Pets Since 1868]

[For use ONLY on dogs]

[Formulated for Dogs and Puppies Over 7 Weeks [Old][of Age] and 4 lbs]

[Formulated for Dogs and Puppies 7 Weeks [of Age] or Older and 4 lbs]

[Dogs and Puppies over 7 weeks [old][of age] and 4 lbs]

[Dogs and Puppies 7 weeks [of age] or older and 4 lbs]

[Use only on puppies over 7 weeks [old][of age][or] 7 weeks [of age] or older and 4 lbs]

[The Only Monthly Flea Protection You Need For Your Dog[s] When Applied Monthly!]

Sergeant's® Master Label

15 January 2016

Version 15.1

EPA Reg. No. 2517-RTU

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Page 5 of 11

[Convenient]

[Easy application]

[Easy to apply product]

[Easy to Use [Application]]

[One Step Hassle Free Protection!]

[Waterproof]

[Remains effective even after shampooing, swimming, or exposure to sunlight [and][or] [rain]

[Remains effective, even after bathing, water immersion, or exposure to [sunlight] [and][or] rain]

[Once a month treatment]

[Apply once every [4 weeks] [month] [30 days]!]

[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]

[For year-round protection, apply [Brand Name][this product] monthly]

[One tube [vial][pipette]] [1 Month Supply]

[Two tubes [vials][pipettes]] [2 Month Supply]

[Three tubes [vials][pipettes]] [3 Month Supply]

[Four tubes [vials][pipettes]] [4 Month Supply]

[Five tubes [vials][pipettes]] [5 Month Supply]

[Six tubes [vials][pipettes]] [6 Month Supply]

[9 tubes [vials][pipettes]] [9 Month Supply]

[12 tubes [vials][pipettes]] [12 Month Supply]

[24 tubes [vials][pipettes]] [24 Month Supply]

[Direct to skin [tube][vial][applicator][pipette]]

[Easy to Use] [tube][vial][applicator][pipette]

[No-mess [open] [tube][vial][applicator][pipette]]

[Clip-tip design [tube][vial][applicator][pipette][!]]

{END – FRONT PANEL}

Sergeant's[®] Master Label

15 January 2016

Version 15.1

EPA Reg. No. 2517-RTU

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Information in { } is note to reviewer.

Page 6 of 11

BACK PANEL/SIDE PANEL

Dogs Squeeze On Imidacloprid

[The active ingredient in [Brand name][this product] is [imidacloprid,] formulated for control of fleas on dogs.] [[Brand Name][This product] kills fleas within 12 hours and prevents further flea infestations for [up to] [[4][four] weeks][[1][one] month][30 days].]

READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON DOGS AND PUPPIES 7 WEEKS OF AGE OR OLDER.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. WARNING. Causes substantial but temporary eye injury. Harmful if swallowed. Harmful if absorbed through the skin. Avoid contact with skin. Do not get in eyes or on clothing. Wash hands after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities, while rare, may occur after using ANY pesticide product for dogs. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing dogs.

FIRST AID	
If In Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If Swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on Skin or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

Sergeant's[®] Master Label

15 January 2016

Version 15.1

EPA Reg. No. 2517-RTU

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Page 7 of 11

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

Restrictions:

- **DO NOT ALLOW CHILDREN TO APPLY PRODUCT.**
- Do not use on animals other than dogs.
- Do not allow your dog to ingest this product.
- Do not reapply for [[four][4] weeks][30 days].
- Do not use on puppies under 7 weeks of age or less than 4 [11] [21] [55] lbs.
- Use entire contents of tube[vial][applicator][pipette] on each dog. Do not split one tube[vial][applicator][pipette] between two dogs. Do not use multiple tube[vial][applicator][pipette]s on one dog.
- Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog.
- Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.
- Do not have contact or allow children to have contact with the treated area until completely dry.

{Side Effects box to be located on label above the cat prohibition icon/text all on the lower right hand side of the back panel}

Side Effects: Monitor your dog after application. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your dog and continue to monitor your dog for the next 24 hours.



[1.5 cm x 1.5 cm on final or as indicated]

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. Contact your veterinarian if applied to a cat or ingested by a cat.

Sergeant's[®] Master Label

15 January 2016

Version 15.1

EPA Reg. No. 2517-RTU

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Page 8 of 11

{OUTER PACKAGING}

How to Open:

1. Remove product tube[s][vial[s]][applicator[s]][pipette[s]] from the package.
2. Separate one tube[vial][applicator][pipette] from the others. Hold the tube[vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Invert tube[vial][applicator][pipette] over dog and use open end to part dog's hair.
2. Squeeze tube[vial][applicator][pipette] firmly to apply all of the solution [on] [to] the dog's skin [as a spot to the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

{For cartons containing 0.4 mL (0.014 fl oz) applicator tubes}

Only For Dogs Weighing 4 [] [to] 10 lbs. Do not apply to dogs weighing less than 4 lbs.

[including small dogs and puppies, only 7 weeks or older] Apply one

tube[vial][applicator][pipette] 0.4 mL (0.014 fl oz) directly to skin [either] [as a spot [on] [to] the dog's back between the shoulder blades] [or] [as a [stripe][line] starting from the back of the neck to a point midway between the neck and tail].

{For cartons containing 1.0 mL (0.034 fl oz) applicator tube}

Only For Dogs Weighing 11 [] [to] 20 lbs. Do not apply to dogs weighing less than 11 lbs.

Apply one tube[vial][applicator][pipette] 1.0 mL (0.034 fl oz) directly to skin [either] [as a spot [on] [to] the dog's back between the shoulder blades] [or] [as a [stripe][line] starting from the back of the neck to a point midway between the neck and tail].

{For cartons containing 2.5 mL (0.085 fl oz) applicator tube}

Only For Dogs Weighing 21 [] [to] 55 lbs. Do not apply to dogs weighing less than 21 lbs.

Apply one tube[vial][applicator][pipette] 2.5 mL (0.085 fl oz) directly to skin [either] [as a spot [on] [to] the dog's back between the shoulder blades] [or] [as a [stripe][line] starting from the back of the neck to a point midway between the neck and tail].

{For cartons containing 4.0 mL (0.135 fl oz) applicator tube}

Only For Dogs Weighing 55 lbs. or greater. Do not apply to dogs weighing less than 55 lbs.

Do not use more than one [tube][vial][applicator][pipette] on dogs greater than 55 lbs.

Apply one tube[vial][applicator][pipette] 4.0 mL (0.135 fl oz) directly to skin [either] [as a spot [on] [to] the dog's back between the shoulder blades] [or] [as a [stripe][line] starting from the back of the neck to a point midway between the neck and tail].

FREQUENCY OF APPLICATION

[Use [Brand Name {or} this product] monthly for control of flea[s] [infestations].]

[[Studies show that] [Brand Name][This product] kills fleas within 12 hours of application and [lasts {or} protects] [for [up to] [[four][4] weeks][30 days][one month].]

[[Brand Name {or} This product] kills reinfesting fleas within [2][two] hours and prevents further infestations of fleas [for [up to] [[four][4] weeks][30 days][one month]].]

[If your dog is at high risk for flea reinfestation [, or in a highly infested environment], apply monthly.]

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Information in [] is optional.

Information in { } is note to reviewer.

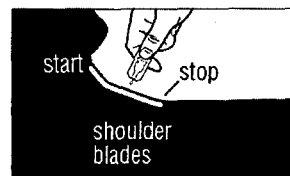
Page 9 of 11

[Apply monthly for optimal flea control.]

[[Brand Name {or} This product] is waterproof and remains effective, even after bathing, swimming, or exposure to sunlight [and][or] [rain].]

[Allow treated area to dry thoroughly.]

[How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling. Refer to following optional graphics.]



STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove [tube][vial][applicator][pipette] from the pack until ready to use. Store only in original container in a cool [(below 77°F/[25°C])], dry area inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: **If empty:** Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's][SENTRY][PetArmor®]Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

[Satisfaction Guaranteed][If you are not satisfied, we will make it right with a replacement or refund.]

In Case of Emergency, call: 1-800-781-4738

Non-Emergency, call: 1-800-224-PETS (7387)

[Coupon(s) inside or on outside of box]

[Made in USA With Global Materials]

[Distributed by:] [Manufactured by:]

Sergeant's Pet Care Products, Inc.

Omaha, NE 68138-3710

{END - BACK PANEL/SIDE PANEL}

EPA Reg. No. 2517-RTU

EPA Est. No. XXXXX-XX-XX

[BAR CODE AREA]

Sergeant's® Master Label

15 January 2016

Version 15.1

EPA Reg. No. 2517-RTU

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Page 10 of 11

{START – ADDITIONAL OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE OR INSERT}

[Clip. Part. Squeeze.]

Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting proven flea protection where it needs to be.]

[Application Instructions]

How to Open:

1. Remove product tube[s][vial[s]][applicator[s]][pipette[s]] from the package.
2. Separate one tube[vial][applicator][pipette] from the others. Hold the tube[vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Invert tube[vial][applicator][pipette] over dog and use open end to part dog's hair.
2. Squeeze tube[vial][applicator][pipette] firmly to apply all of the solution [on] [to] the dog's skin [as a spot to the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

[Look at the Label [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist]

- [1] Read the label completely and follow directions
- [2] Weigh your dog
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after treatment [application] to avoid chance of ingestion
- [6] Do NOT split tube[vial][applicator][pipette] between dogs[and use the ENTIRE tube[vial][applicator][pipette] contents]

[Brand Name][This product]

[Monthly reminder card]

[1][2][3][4][5][6][12][24][Month [Treatment] [Application] Tracker][Carecard]

[For year-round protection, apply [Brand Name][this product] monthly.]

[Dog's Name (Empty blank for owner to fill in name)]

[Dog's Weight (Empty blank for owner to fill in name)]

[First][1st][Second][2nd][Third][3rd][Fourth][4th][Fifth][5th][Sixth][6th][Seventh][7th][Eighth][8th][Ninth][9th][Tenth][10th][Eleventh][11th][Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)

[Application Date][Date of Application]

[Calendar stickers with Brand Name]

[Place stickers on your calendar as a reminder to reapply [Brand Name][this product] [in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Place sticker on your calendar [or refrigerator] to remind yourself to apply [Brand Name][this product] to your dog]

Sergeant's® Master Label

15 January 2016

Version 15.1

EPA Reg. No. 2517-RTU

Information in [] is optional.

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Page 11 of 11





[33% More Free]

[Bonus Size]

[Buy 3 get 1 free]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [Brand Name][this product]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

[Each optional graphic below may or may not appear anywhere on the finished label]

	Adult Flea	
	Fleas	



**DO NOT USE
ON CATS**



{non-mandatory optional graphics that may be used in addition to the EPA mandatory icon requirements that currently appear on the label.}

*Refund or replacement of product {text footnote to satisfaction guaranteed graphic}

**MADE IN THE
USA**
WITH GLOBAL MATERIALS

{END – ADDITIONAL OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE OR INSERT}

Sergeant's[®] Master Label

15 January 2016

Version 15.1

EPA Reg. No. 2517-RTU

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Page 12 of 11

TUBE/VIAL LABEL

**Dogs Squeeze On
Imidacloprid**

{Front Label}

{Back Label}

<p>[Brand Name (for dogs)] X-Y lbs. \geq 7 wks Imidacloprid 9.10% 0.014 fl oz (or) 0.034 fl oz (or) 0.085 fl oz (or) 0.135 fl oz {label code}</p>	<p> KEEP OUT OF REACH OF CHILDREN WARNING: Read directions and precautions on packaging. Use scissors to open. EPA REG. No. 2517-RTU {label code}</p>
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

{EPA REG No may be on either the front or back label}

{label code refers to Sergeant's product code number assigned to each product}

{END – TUBE/VIAL LABEL}

Kumar, Rita

From: Carrie Daniels <cdaniels@exponent.com>
Sent: Friday, January 15, 2016 12:15 PM
To: Kumar, Rita
Cc: James Messina; Eagle, Venus
Subject: 2517-RTU
Attachments: 2517-RTU Revised Label 1-15-16 track.docx; 2517-RTU Revised Label 1-15-16 clean.docx; 2517-RTU Revised Label 1-15-16 clean.pdf

Dear Rita,

Following our conversation this morning, I have attached the revised product label for Sergeants pending product 2517-RTU (track changes and clean, with PDF to show color). As we discussed, the following changes have been made:

- The cat icon has been revised so that the cat is within a square box. The cat/strike through will be sized to meet the 1.5 x 1.5 requirements. Please note that Sergeants has the additional text "Do not use on cats" as compared to their competitors, who only have a box around the cat strike through and not the words.
- On the front vial label, the weight range is not optional.
- On the back vial label, the referral statement reads: "Read directions and precautions on package."
- As we discussed, we have included the "Made in the USA with Global Materials" graphic as you indicated this was acceptable for the cat label. I have also included the optional statement "Made in the USA with Global Materials" on page 10 of the track changes label.
- The note to reviewer for the footnote to the Satisfaction Guaranteed graphic was revised to read "{text footnoted to satisfaction guaranteed graphic}" to make is clear that this footnote will accompany the graphic.

Please do not hesitate to call me if you have any questions regarding this label and the changes as discussed.

Sincerely,
Carrie

Carrie Daniels
Senior Managing Regulatory Consultant
Exponent, Inc.
202-772-4916

Draft

Kumar, Rita

From: Carrie Daniels <cdaniels@exponent.com>
Sent: Wednesday, January 13, 2016 6:19 PM
To: Kumar, Rita
Cc: Eagle, Venus; James Messina
Subject: 2517-RTU
Attachments: 2517-RTU Revised Label 1-13-16 clean.docx; 2517-RTU Revised Label 1-13-16 track.docx

Rita,

Following up on our conversation on Tuesday, I have attached the revised product labels for Sergeants pending product 2517-RTU (track changes and clean). As you had requested, I have revised the phrase:

[Do not use two [tube][vial][applicator][pipette]s on dogs greater than 55 lbs.]

To read:

Do not use more than one [tube][vial][applicator][pipette] on dogs greater than 55 lbs.

My understanding is that the above change was the final revision needed for this product label. Please let me know if you have any questions.

Sincerely,
Carrie

Carrie Daniels
Senior Managing Regulatory Consultant
Exponent, Inc.
202-772-4916

Draft 1/13/16

revisions needed. called Carrie

Sergeant's® Master Label

09135 January/December 20165

Version 15.1

EPA Reg. No. 2517-RTU

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Page 1 of 11

FRONT PANEL

Dogs Squeeze On Imidacloprid

[Optional text appears in brackets/parenthesis – the final label may include some or all of the optional text on front, back or side label panels]

Sergeant's® 9.1% Imidacloprid Squeeze On for Dogs

{Market Label-the word Dog will be at least 40-75% in height of the largest letter in the primary brand name.}

{Market Label a large clear picture of a dog in the respective weight range will be on the front panel of the label for the product as packaged.}

{One of the following statements will appear on appropriate weight band market label on front panel as required per Agency's pet spot-on mitigation measures:}

For use ONLY on dogs [[&][and] puppies] [weighing] $\frac{3}{4}$ [-][to] 10 lbs. and over 7 weeks

[old][of age] {0.4 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] $\frac{4\frac{1}{2}}$ [-][to] 10 lbs. and 7 weeks [of age] or older {0.4 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 11 [-][to] 20 lbs. and over 7 weeks

[old][of age] {1.0 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 11 [-][to] 20 lbs. and 7 weeks [of age] or older {1.0 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 21 [-][to] 55 lbs. and over 7 weeks

[old][of age] {2.5 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 21 [-][to] 55 lbs. and 7 weeks [of age] or older {2.5 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] [more than][over][>] 55 lbs. and over 7 weeks [old][of age] {4.0 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] [more than][over][>] 55 lbs. and 7 weeks [of age] or older {4.0 ml size package}

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] $\frac{3}{4}$ [-][to] 10 lbs. {0.4 ml size package}

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] $\frac{3}{4}$ [-][to] 10 lbs. {0.4 ml size package}

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] 11 [-][to] 20 lbs. {1.0 ml size package}

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] 11 [-][to] 20 lbs. {1.0 ml size package}

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] 21 [-][to] 55 lbs. {2.5 ml size package}

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] 21 [-][to] 55 lbs. {2.5 ml size package}

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] [more than][over][>] 55 lbs. {4.0 ml size package}

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] [more than][over][>] 55 lbs. {4.0 ml size package}

[1.5cm x 1.5cm on final or as indicated]



size of package must be indicated w/ animal wt & age. Cannot be optional.

Must be a square, and in color on the clean copy.

Sergeant's® Master Label

09135 January/December 20165

Version 15.1

EPA Reg. No. 2517-RTU

Information in [] is optional.

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Page 2 of 11

*Basic
Product Name?*

ACTIVE INGREDIENT:

Imidacloprid.....9.10%

OTHER INGREDIENTS:90.90%

[TOTAL]100.00%

KEEP OUT OF REACH OF CHILDREN

WARNING

See [Back][or][Side][Label[s]][Panel[s]] for Additional Precautionary Statements

NET CONTENT: X fl oz [Y – X fl oz applicators]

[0.014 fl oz (0.4 mL) [tubes][vials][applicators][pipettes]]

[0.034 fl oz (1.0 mL) [tubes][vials][applicators][pipettes]]

[0.085 fl oz (2.5 mL) [tubes][vials][applicators][pipettes]]

[0.135 fl oz (4.0 mL) [tubes][vials][applicators][pipettes]]

[ABNs]

[SENTRY® Vet for Dogs Imidacloprid]

[SENTRY® Vet Advanced Flea for Dogs]

[SENTRY® Vet FleaGuard for Dogs]

[SENTRY® Vet Vantage for Dogs]

[SENTRY® Vet Flea Vantage for Dogs]

[SENTRY® Advanced for Dogs Imidacloprid]

[SENTRY® Advanced FleaGuard for Dogs]

[SENTRY® Advanced Vantage for Dogs]

[SENTRY® Advanced Flea Vantage for Dogs]

[SENTRY® Advanced VetSpot for Dogs]

[PetArmor® Vantage for Dogs]

[PetArmor® Advant for Dogs]

[PetArmor® FleaGuard for Dogs]

[PetArmor® Advanced for Dogs]

[PetArmor® Flea Vantage for Dogs]

[PetArmor® Adv Flea for Dogs]

[PetArmor® Adv.Flea for Dogs]

[PetArmor® AdvVet for Dogs]

[Begin Optional Active Ingredient Reference Statements]

{Note to Reviewer – the following is an example statement:

Contains imidacloprid, the active ingredient used in Advantage® 10 Topical Solution*

*[This product is not manufactured by Bayer Healthcare LLC, the makers of Advantage® 10 Topical Solution] [OR] [Advantage® 10 Topical Solution is a registered trademark of Bayer Healthcare LLC]

{Contains imidacloprid, [the] [same] active ingredient used in

{OR}

{Contains [the] [same] active ingredient used in

{OR}

{[Brand Name] [This product] contains [imidacloprid], [the] [same] active ingredient used in

{OR}

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Sergeant's® Master Label

09135 January/December 20165

Version 15.1

EPA Reg. No. 2517-RTU

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Information in { } is note to reviewer.

Page 3 of 11

~~[Advantage® 10 Topical Solution] [Advantage® for Small Dogs] [Advantage® TM 10
(Imidacloprid) Topical Solution]~~

~~{OR}~~

~~[Advantage® 20 Topical Solution] [Advantage® for Medium Dogs] [Advantage® TM 20
(Imidacloprid) Topical Solution]~~

~~{OR}~~

~~[Advantage® 55 Topical Solution] [Advantage® for Large Dogs] [Advantage® 55 (Imidacloprid)
Topical Solution]~~

~~{OR}~~

~~[Advantage® 100 Topical Solution] [Advantage® for Extra Large Dogs] [Advantage® 100
(Imidacloprid) Topical Solution].~~

~~*†~~

{Note to reviewer: Text for footnote statement one}

**[*~~[Brand Name]~~This product] is not manufactured or distributed by Bayer Healthcare
LLC, the makers of**

~~[Advantage® 10 Topical Solution] [Advantage® for Small Dogs] [Advantage® TM 10
(Imidacloprid) Topical Solution]~~

~~{OR}~~

~~[Advantage® 20 Topical Solution] [Advantage® for Medium Dogs] [Advantage® TM 20
(Imidacloprid) Topical Solution]~~

~~{OR}~~

~~[Advantage® 55 Topical Solution] [Advantage® for Large Dogs] [Advantage® 55 (Imidacloprid)
Topical Solution]~~

~~{OR}~~

~~[Advantage® 100 Topical Solution] [Advantage® for Extra Large Dogs] [Advantage® 100
(Imidacloprid) Topical Solution]. *]~~

{Note to reviewer: Text for footnote statement two}

~~[*~~[Advantage® 10 Topical Solution] [Advantage® for Small Dogs] [Advantage® TM 10
(Imidacloprid) Topical Solution],~~~~

~~{OR}~~

~~[Advantage® 20 Topical Solution] [Advantage® for Medium Dogs] [Advantage® TM 20
(Imidacloprid) Topical Solution],~~

~~{OR}~~

~~[Advantage® 55 Topical Solution] [Advantage® for Large Dogs] [Advantage® 55 (Imidacloprid)
Topical Solution],~~

~~{OR}~~

~~[Advantage® 100 Topical Solution] [Advantage® for Extra Large Dogs] [Advantage® 100
(Imidacloprid) Topical Solution]~~

is a registered trademark of Bayer Healthcare LLC.]

[End Optional Active Ingredient Reference Statements]

[Fleas]

[Prevents further flea infestation for up to [[four][4] weeks][1 month] with one treatment]

[Prevents further flea infestation for up to [[four][4] weeks][1 month] with one application]

[Brand Name] Prevents flea infestation for [four][4] weeks][1 month]

Sergeant's® Master Label

09135 January/December 2016s

Version 15.1

EPA Reg. No. 2517-RTU

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Page 4 of 11

[Kills fleas within 12 hours [of application] on dogs]

[Kills reinfesting fleas within 2 hours]

[Kills [adult] fleas before they lay eggs]

[[Brand Name][This product] kills fleas and may reduce the incidence of a hypersensitivity skin disorder called flea allergy dermatitis (FAD), which may be caused by the feeding activity of fleas.]

[Use [of Brand Name][of this product] kills fleas and may reduce incidence of flea bite hypersensitivity] [and][or] [flea allergy dermatitis] [FAD]]

[Use [of Brand Name][of this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]

[Monthly treatment [with Brand Name][with this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]

[Monthly treatment [with Brand Name][with this product] kills fleas and may reduce incidence of flea bite hypersensitivity [and][or] [flea allergy dermatitis] [FAD]]

~~[Kills flea larvae in dog's environment following contact with treated dog]~~

[Apply monthly [for optimal flea control]]

[Apply monthly [to control and prevent fleas]]

[Kills fleas]

[Kills fleas within 12 hours, continues to kill for up to 4 weeks]

[Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation]

[Kills fleas, which may be a source of flea allergy dermatitis in 12 hours]

~~[Flea protection]~~

[Active against fleas]

[Kills fleas on [puppies and] dogs]

[[Brand Name] Offers protection against fleas]

[Flea control for puppies and dogs {over 7 weeks [old]}[of age] and 4 lbs]

[Flea control for puppies and dogs {7 weeks [of age] or older} and 4 lbs]

[Kills fleas within 12 hours [and prevents ~~further~~ flea infestations for [a][one] [month] [four weeks]]]

[All Others]

[Apply to [dogs and] puppies over 7 weeks old and 4 lbs]

[Apply to [dogs and] puppies 7 weeks or older and 4 lbs]

[SENTRY®]

[PetArmor®]

[[Sergeant's] Caring For Your Pets Since 1868]

[For use ONLY on dogs]

~~[Specially Formulated for Dogs and Puppies {Over 7 Weeks [Old]}[of Age] and 4 lbs]~~

~~[Specially Formulated for Dogs and Puppies {7 Weeks [of Age] or Older} and 4 lbs]~~

[Dogs and Puppies {over 7 weeks [old]}[of age] and 4 lbs]

[Dogs and Puppies {7 weeks [of age] or older} and 4 lbs]

[Use only on puppies {over 7 weeks [old]}[of age] and 4 lbs]

[The Only Monthly Flea Protection You Need For Your Dog[s] When Applied Monthly!]

[Convenient]

[Easy application]

[Easy to apply product]

[Easy to Use [Application]]

[One Step Hassle Free Protection!]

[Waterproof]

Sergeant's® Master Label

09/35 January/December 2016s

Version 15.1

EPA Reg. No. 2517-RTU

Information in [] is optional.

Information in { } is note to reviewer.

Page 5 of 11

[Remains effective even after shampooing, swimming, or exposure to sunlight [and][or] [rain]
[Remains effective, even after bathing, water immersion, or exposure to [sunlight] [and][or] rain]
[Once a month treatment]

[Apply once every [4 weeks] [month] [30 days]!]

[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]

[For year-round protection, apply [Brand Name][this product] monthly]

{Best if used year round!}

[X Applicationstubes [vials][pipettes]] [X-Week Supply] [X-Month Supply]

[One Applicationtube [vial][pipette]] [4-Week Supply] [1 Month Supply]

[Two Applicationstubes [vials][pipettes]] [8-Week Supply] [2 Month Supply]

[Three Applicationstubes [vials][pipettes]] [12-Week Supply] [3 Month Supply]

[Four Applicationstubes [vials][pipettes]] [16-Week Supply] [4 Month Supply]

[Five Applicationstubes [vials][pipettes]] [20-Week Supply] [5 Month Supply]

[Six Applicationstubes [vials][pipettes]] [24-Week Supply] [6 Month Supply]

[9 Applicationstubes [vials][pipettes]] [36-Week Supply] [9 Month Supply]

[12 Applicationstubes [vials][pipettes]] [52-Week Supply] [12 Month Supply]

[24 Applicationstubes [vials][pipettes]] [104-Week Supply] [24 Month Supply]

{for} Small Dog[s] {3.5}[3½] {to} [10 lbs.}]

{for} Medium Dog[s] [11] {to} [20 lbs.}]

{for} Large Dog[s] [21] {to} [55 lbs.}]

{for} Extra Large Dog[s] {Over 55 lbs.}]

[Direct to skin [tube][vial][applicator][pipette]]

[Easy to Use] [tube][vial][applicator][pipette]

[Clean cut [open] [tube][vial][applicator][pipette]]

[No-mess [open] [tube][vial][applicator][pipette]]

[Clip-tip design [tube][vial][applicator][pipette] [!]]

{END – FRONT PANEL}

BACK PANEL/SIDE PANEL OR INSERT

**Dogs Squeeze On
Imidacloprid**

[The active ingredient in [Brand name][this product] is [imidacloprid,] formulated for fast-acting
{and long-lasting} control of fleas on dogs.] [[Brand Name][This product] kills fleas within 12
hours and prevents further flea infestations for [up to] [[4][four] weeks][1][one] month][30
days].]

READ ENTIRE LABEL BEFORE EACH USE.

USE ONLY ON DOGS AND PUPPIES 7 WEEKS OF AGE OR OLDER.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. WARNING. Causes substantial but temporary eye injury. ~~Do not
get in eyes or on clothing.~~ Harmful if swallowed. Harmful if absorbed through the skin. Avoid
contact with skin. ~~Do not get in eyes or on clothing.~~ Wash hands after handling and before
eating, drinking, chewing gum, using tobacco or using the toilet thoroughly with soap and warm
water after handling.

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HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual
sensitivities, while rare, may occur after using ANY pesticide product for dogs. Do not treat your
dog with more than one pesticide product at a time. Over dosing your dog can result in serious

Sergeant's® Master Label

09135 January/December 20165

Version 15.1

EPA Reg. No. 2517-RTU

Information in [] is optional.

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Page 6 of 11

illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing dogs.

FIRST AID

If In Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If Swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on Skin or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.

NOTE TO PHYSICIAN

Treat the patient symptomatically.

Sergeant's® Master Label

09135 January/December 20165

Version 15.1

EPA Reg. No. 2517-RTU

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Page 7 of 11

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

~~DO NOT ALLOW CHILDREN TO APPLY PRODUCT.~~ TO PREVENT HARM TO YOU

AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL

DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

Restrictions:

- ~~DO NOT ALLOW CHILDREN TO APPLY PRODUCT.~~

Formatted: Font: Not Bold, Not All caps

- Do not use on animals other than dogs.
- Do not allow your dog to ingest this product.
- ~~{Do not reapply for [four][4] weeks}[30 days].}~~
- Do not use on puppies under 7 weeks of age or less than 43.54[3 1/2] [11] [21] [55] lbs.
- Use entire contents of tube[vial][applicator][pipette] on each dog. Do not split one tube[vial][applicator][pipette] between two dogs. Do not use multiple tube[vial][applicator][pipette]s on one dog.
- Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog.
- Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.
- Do not have contact or allow children to have contact with the treated area until completely dry.

{Side Effects box to be located on label above the cat prohibition icon/text all on the lower right hand side of the back panel}

Side Effects: Monitor your dog after application. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your dog and continue to monitor your dog for the next 24 hours.



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[1.5 cm x 1.5 cm on final or as indicated]

~~DO NOT USE ON CATS.~~ Keep cats away from treated dogs for 24 hours. Contact your veterinarian if applied to a cat or ingested by a cat.

Sergeant's® Master Label

09135 January/December 20165

Version 15.1

EPA Reg. No. 2517-RTU

Information in [] is optional.

Information in { } is note to reviewer.

Page 8 of 11

{OUTER PACKAGING}

How to Open:

1. Remove product tube[s][vial[s]][applicator[s]][pipette[s]] from the package.
2. Separate one tube[vial][applicator][pipette] from the others. Hold the tube[vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

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How to Apply:

1. Invert tube[vial][applicator][pipette] over dog and use open end to part dog's hair.
2. Squeeze tube[vial][applicator][pipette] firmly to apply all of the solution [on] [to] the dog's skin [as a spot to the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.] ~~from a point midway between the neck and tail to the back of the neck.~~

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How to Open: Remove product [tube[s]][vial[s]][applicator[s]][pipette[s]] from the package. [Separate one [tube[vial][applicator][pipette] from the others.] Hold the [tube[vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply: Invert [tube[vial][applicator][pipette] over dog and use open end to part dog's hair. Squeeze [tube[vial][applicator][pipette] firmly to apply all of the solution to the dog's skin, as directed below. Do not apply more often than once every [30 days][4 weeks][month].

{For cartons containing 0.4 mL (0.014 fl oz) applicator tubes}

Only For Dogs Weighing [3.5][3½] [-][to] 10 lbs. Do not apply to dogs weighing less than [3.5][3½] lbs. [including small dogs and puppies, only 7 weeks or older] Apply one tube[vial][applicator][pipette] 0.4 mL (0.014 fl oz) directly to skin [either] [as as a spot [on] [to] the dog's back between the shoulder blades] [or] [as a [stripe][line] starting ~~at~~ from the back of the neck to a point midway between the neck and tail.] ~~a midway point between the neck and tail to the back of the neck.~~ Apply one [tube[vial][applicator][pipette] 0.4 mL (0.014 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail] [as a spot [on][to] the dog's back between the shoulder blades][as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades.] [This allows for a more direct application to the skin.]

{For cartons containing 1.0 mL (0.034 fl oz) applicator tube}

Only For Dogs Weighing 11 [-][to] 20 lbs. Do not apply to dogs weighing less than 11 lbs. Apply one tube[vial][applicator][pipette] 1.0 mL (0.034 fl oz) directly to skin [either] [as as a spot [on] [to] the dog's back between the shoulder blades] [or] [as a [stripe][line] starting from the back of the neck to a point midway between the neck and tail.] ~~at a midway point between the neck and tail to the back of the neck.~~ Apply one [tube[vial][applicator][pipette] 1.0 mL (0.034 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail] [as a spot [on][to] the dog's back between the shoulder blades][as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades.] [This allows for a more direct application to the skin.]

{For cartons containing 2.5 mL (0.085 fl oz) applicator tube}

Only For Dogs Weighing 21 [-][to] 55 lbs. Do not apply to dogs weighing less than 21 lbs.

Sergeant's® Master Label

09135 January/December 2016/5

Version 15.1

EPA Reg. No. 2517-RTU

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Page 9 of 11

Apply one tube[vial][applicator][pipette] 2.5 mL (0.085 fl oz) directly to skin [either] [as as a spot [on] [to] the dog's back between the shoulder blades] [or] [as a [stripe][line] starting from the back of the neck to a point midway between the neck and tail at a midway point between the neck and tail to the back of the neck]. Apply one [tube][vial][applicator][pipette] 2.5 mL (0.085 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail] [as a spot [on][to] the dog's back between the shoulder blades] [as a [stripe][line] starting [at the middle of the back] [at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades. [This allows for a more direct application to the skin.]

{For cartons containing 4.0 mL (0.135 fl oz) applicator tube}

Only For Dogs Weighing 55 lbs. or greater. Do not apply to dogs weighing less than 55 lbs.

{Do not use more than one two [tube][vial][applicator][pipette]s on dogs greater than 55 lbs.}

Apply one tube[vial][applicator][pipette] 4.0 mL (0.135 fl oz) directly to skin [either] [as as a spot [on] [to] the dog's back between the shoulder blades] [or] [as a [stripe][line] starting from the back of the neck to a point midway between the neck and tail at a midway point between the neck and tail to the back of the neck]. Apply one [tube][vial][applicator][pipette] 4.0 mL (0.135 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail] [as a spot [on][to] the dog's back between the shoulder blades] [as a [stripe][line] starting [at the middle of the back] [at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades. [This allows for a more direct application to the skin.]

FREQUENCY OF APPLICATION

[Use [Brand Name {or} this product] monthly for control of flea[s] [infestations].]

[[Studies show that] [Brand Name][This product] kills fleas within 12 hours of application and

[lasts {or} protects] [for [up to] [[four][4] weeks][30 days][one month].]

[[Brand Name {or} This product] kills reinfesting fleas within [2][two] hours and prevents further infestations of fleas [for [up to] [[four][4] weeks][30 days][one month]].]

[If your dog is at high risk for flea reinfestation [, or in a highly infested environment], apply monthly.]

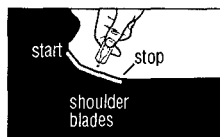
[Apply monthly for optimal flea control.]

[[Brand Name {or} This product] is waterproof and remains effective, even after bathing, swimming, or exposure to sunlight [and][or] [rain].]

[Allow treated area to dry thoroughly.]

~~[Do not reapply for [[four][4] weeks][30 days].]~~

[How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling. Refer to following optional graphics.]



STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove [tube][vial][applicator][pipette] from the pack until ready to use. Store only in original container in a cool [(below 77°F/[25°C])], dry area inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

Sergeant's® Master Label

09135 January/December 2016s

Version 15.1

EPA Reg. No. 2517-RTU

Information in [] is optional.

Information in { } is note to reviewer.

Page 10 of 11

CONTAINER DISPOSAL: **If empty:** Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's][SENTRY][PetArmor®]Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

[Satisfaction Guaranteed][If you are not satisfied, we will make it right with a replacement or refund.]

In Case of Emergency, call: 1-800-781-4738

[Coupon(s) inside or on outside of box]

Non-Emergency, call: 1-800-224-PETS (7387)

{Made in USA [With Global Materials]}

[Distributed by:] [Manufactured by:]

EPA Reg. No. 2517-RTU

Sergeant's Pet Care Products, Inc.

EPA Est. No. XXXXX-XX-XX

Omaha, NE 68138-3710

[BAR CODE AREA]

{END - BACK PANEL/SIDE PANEL OR INSERT}

Sergeant's® Master Label

09135 January/December 20165

Version 15.1

EPA Reg. No. 2517-RTU

Information in [] is optional.

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Page 11 of 11

{START – ADDITIONAL OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE OR INSERT}

[How to Apply – May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.]

[Clip. Part. Squeeze.]

Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting proven flea protection where it needs to be.]

[Application Instructions]

How to Open:

1. Remove product tube[s][vial[s]][applicator[s]][pipette[s]] from the package.
2. Separate one tube[vial][applicator][pipette] from the others. Hold the tube[vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

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How to Apply:

1. Invert tube[vial][applicator][pipette] over dog and use open end to part dog's hair.
2. Squeeze tube[vial][applicator][pipette] firmly to apply all of the solution [on] [to] the dog's skin [as a spot to the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

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[Look at the Label (Look at the Label icon) [Easy] 6 Step [Easy] [Spot On] [Squeeze-On]

[Topical] Checklist]

- [1] Read the label completely and follow directions
- [2] Weigh your dog
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after treatment [application] to avoid chance of ingestion
- [6] Do NOT split tube[vial][applicator][pipette] between dogs[and use the ENTIRE tube[vial][applicator][pipette] contents]

[Brand Name][This product]

[Monthly reminder card]

[1][2][3][4][5][6][12][24][Month [Treatment] [Application] Tracker][Carecard]

[For year-round protection, apply [Brand Name][this product] monthly.]

[Dog's Name (Empty blank for owner to fill in name)]

[Dog's Weight (Empty blank for owner to fill in name)]

[First][1st][Second][2nd][Third][3rd][Fourth][4th][Fifth][5th][Sixth][6th][Seventh][7th][Eighth]

[8th][Ninth][9th][Tenth][10th][Eleventh][11th][Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)

[Application Date][Date of Application]

[Calendar stickers with Brand Name]

[Place stickers on your calendar as a reminder to reapply [Brand Name][this product] [in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Place sticker on your calendar [or refrigerator] to remind yourself to apply [Brand Name][this product] to your dog]

Sergeant's® Master Label

09135 January-December 20165

Version 15.1

EPA Reg. No. 2517-RTU

Information in [] is optional.

Information in { } is note to reviewer.

Page 12 of 11







[33% More Free]

[Bonus Size]

[Buy 3 get 1 free]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [Brand Name][this product]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

[Each optional graphic below may or may not appear anywhere on the finished label]

	Adult Flea	
	Fleas	
	Flea Larvae	



Adult Dog



DO NOT USE
ON CATS



* add

{non-mandatory optional graphics that may be used in addition to the EPA mandatory icon requirements that currently appear on the label.}

*Refund or replacement of product {text footnote to graphic}

{END – ADDITIONAL OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE OR INSERT}

TUBE/VIAL LABEL

Dogs Squeeze On
Imidacloprid

Sergeant's® Master Label

09135 January/December 20165

Version 15.1

EPA Reg. No. 2517-RTU

Information in [] is optional.

Information in { } is note to reviewer.

Page 13 of 11

{Front Label}

{Back Label}

[Brand Name (for dogs)]

[X-Y] lbs. ≥ 7 wks

Imidacloprid 9.10%

0.014 fl oz (or) 0.034 fl oz (or) 0.085 fl oz

(or) 0.135 fl oz {label code}



KEEP OUT OF REACH OF CHILDREN

WARNING: Read directions and precautions before using. Use scissors to open.

EPA REG. No. 2517-RTU

{label code}

{EPA REG No may be on either the front or back label}

{label code refers to Sergeant's product code number assigned to each product}

{END - TUBE/VIAL LABEL}

Referral statement is missing. Must be added.

LRM chapter 18,

*Product
brackets around X & Y ^{the} for animal should n't be optional (we feel)*

1-7-2016

Note To File

2517- RTG ~~2517-~~
2517- RTU

1. Similarity Clinic required that this product be placed in child resistant packaging^(CRP). Since all acute toxicity data were cited, and the cited product is not in CRP, we decided to not require CRP for this ~~subject~~ product. This also applies to 2517- RTU.
↳ since cited product had the same profile and was in CRP.
2. Even though product chemistry review states that ~~all~~ the basic and all alternate formulations (1, 2 & 3) ~~data~~ are acceptable, we decided to only accept 1 ^{12/19/2014} the alternate # 1, because the source product in alt. # 1
[REDACTED]
[REDACTED] This alt. # 1 was resubmitted as the new basic CSF dated 12/30/2015 by the registrant.

Product ingredient source information may be entitled to confidential treatment

Kumar, Rita

From: James Messina <jmessina@exponent.com>
Sent: Tuesday, January 05, 2016 10:06 AM
To: Kumar, Rita
Cc: Benbow, Gene; Carrie Daniels; Lewis, Marianne; Eagle, Venus
Subject: RE: 2517-RTU and 2517-RTG
Attachments: 2518-RTU Basic CSF 12-30-15.pdf; 8570-27 Form Ex 2517-RTU imidacloprid.pdf; 2517-RTG Basic CSF 12-30-15.pdf; 8570-27 Form Ex 2517-RTG imidacloprid.pdf

Dear Rita,

Please find attached the updated forms and basic CSFs.

Please let me know if we have any issues related to timing. The PRIA clock ended on 12/10 and as I recall we entered a 30-day period to resolve the label comments. It is our intent to obtain the registrations and we do not want to have any issues related to timing. Please confirm this is not a concern. We have incorporated almost all of EPA's label comments and have noted the following (copy of 12/29 email to Gene):

Dear Gene,

Thank you for contacting me today regarding the two pending Sergeant's product labels. Please find attached the latest label submissions. I have also attached the labels as PDF's.

In your email today you noted the two following comments:

Upper weight limit for the larger package

We note that none of the other EPA approved product labels for imidacloprid containing spot-ons have an upper weight limit on the larger package. This includes the following EPA approved products: 2596-180, 2596-181, 2596-182, 2596-183, 11556-116, 11556-117, 11556-118, 11556-119, 11556-120, 11556-122, 11556-125, 11556-127, 11556-128, 11556-130.

We also note that EPA approved two recent imidacloprid (and PPF) spot-on registrations on December 17, 2015 under 91300-2 and 91300-3. Neither of these EPA approved labels contain an upper weight limit for the larger package. This is found on multiple pages for each of the approved labels:

1. 91300-2: page 1, 3, 5, 7
2. 91300-3: page 1, 3, 6

Based upon the EPA approvals an upper weight limit for the large size is not required.

Do not double-dose animals

This comment has already been addressed on the labels. The attached labels include the following statements (under restrictions):

- Use entire contents of tube[vial][applicator][pipette] on each cat. Do not split one tube[vial][applicator][pipette] between two cats. Do not use multiple tube[vial][applicator][pipette]s on one cat.
- Use entire contents of tube[vial][applicator][pipette] on each dog. Do not split one tube[vial][applicator][pipette] between two dogs. Do not use multiple tube[vial][applicator][pipette]s on one dog.

This language has been previously approved by EPA on other pet spot-on product labels and it addresses this language requirement.



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address

Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

EPA File Symbol/Registration Number

2517-RTU

Product Name

Sergeant's 9.1% Imidacloprid Squeeze On for Dogs

Date of Confidential Statement of Formula (EPA Form 8570-4)

December 30, 2015

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Imidacloprid

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:



(A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1)

OR



(B) The Confidential Statement of Formula (CSF) (EPA Form 8750-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF

(4) The following active ingredients in this product qualify for the formulator's exemption

Source

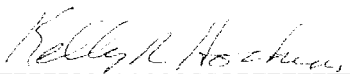
Active Ingredient	Product Name	Registration Number
Imidacloprid [REDACTED]	[REDACTED]	[REDACTED]
Signature 	Name and Title Kelly R. Hoskins, Manager of Regulatory Affairs	Date December 30, 2015



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

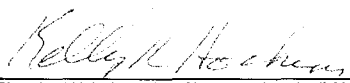
Date: December 19, 2014		EPA Reg No./File Symbol: 2517-NEW		Page 1 of 3	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® 9.1% Imidacloprid Squeeze On for Dogs			
Ingredient: Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry					
830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1750	Group A Product Chemistry for Sergeant's 9.1% Imidacloprid Spot-on Products	49469201	Sergeant's Pet Care Products	OWN	
830.1800	Analytical Method for Sergeant's 9.1% Imidacloprid Spot-On Products	49469202	Sergeant's Pet Care Products	OWN	
830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6319, 830.6321, 830.7000, 830.7100, 830.7300, 830.7520	Summary of Group B Product Chemistry and Waivers for Sergeant's 9.1% Imidacloprid Spot-on Products	49469203	Sergeant's Pet Care Products	OWN	
830.6302, 830.7100, 830.7300	Physical and Chemical Characteristics: Color, Viscosity, and Density for Sergeant's 9.1% Imidacloprid Spot-on Products	49469204	Sergeant's Pet Care Products	OWN	
830.6317, 830.6320	Accelerated 14-Day Storage Stability and Corrosion Characteristics of Sergeant's 9.1% Imidacloprid Spot-on Products	49469205	Sergeant's Pet Care Products	OWN	
830.6315	Flashpoint for Sergeant's 9.1% Imidacloprid and 9.1% Imidacloprid + 0.46% Pyriproxyfen Spot-on Products	49469206	Sergeant's Pet Care Products	OWN	
Toxicology Data Requirements					
870.1100	Acute Oral Toxicity Study with Imidacloprid (Bay T-7391) 10% Pour On in Rats: Lab Project Number: 74585: 95-012-DO. Unpublished study prepared by Bayer Corp. 26 p.	43679601	Bayer HealthCare LLC	OLD	
870.1200	Acute Dermal Toxicity Study with Imidacloprid (Bay T-7391) 10% Pour On in Rats: Lab Project Number: 74584: 95-022-DQ. Unpublished study prepared by Bayer Corp. 24 p.	43679602	Bayer HealthCare LLC	OLD	
870.1300	Acute Four-Hour Inhalation Toxicity Study with Imidacloprid (Bay T-7391) 10% Pour On in Rats: Lab Project Number: 74589: 94-042-CT. Unpublished study prepared by Bayer Corp. 31	43679603	Bayer HealthCare LLC	OLD	
870.2400	Primary Eye Irritation Study with Imidacloprid (Bay T-7391) 10% Pour On in Rabbits: Lab Project Number: 74588: 94-335-CO. Unpublished study prepared by Bayer Corp. 19 p.	43679604	Bayer HealthCare LLC	OLD	
Signature 		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date December 19, 2014	



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401 M Street, S.W.
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DATA MATRIX


Date: December 19, 2014		EPA Reg No./File Symbol: 2517-NEW		Page 2 of 3	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® 9.1% Imidacloprid Squeeze On for Dogs			
Ingredient: Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2500	Primary Dermal Irritation Study with Imidacloprid (Bay T-7391) 10% Pour On in Rabbits: Lab Project Number: 74586: 94-325-CN. Unpublished study prepared by Bayer Corp. 19 p.	43679605	Bayer HealthCare LLC	OLD	
870.2600	Dermal Sensitization Study with Imidacloprid (Bay T-7391) 10% Pour On in Guinea Pigs: Lab Project Number: 74587: 94-324-CW. Unpublished study prepared by Bayer Corp. 24 p.	43679606	Bayer HealthCare LLC	OLD	
870.7200	Acute Toxicity Evaluation for Dermal Treatment of Dogs with Imidacloprid (Bay t 7391) Spot-on: Lab Project Number: 74580: TR-94D-010. Unpublished study prepared by Miles Inc. 19 p.	43679607	Bayer HealthCare LLC	OLD	
870.7200	General Safety Evaluation for Topical Use of Imidacloprid (Bay t 7391) Spot-On On Dogs: Lab Project Number: 74590: TR-95D-005. Unpublished study prepared by Bayer Corp. 40 p.	43679608	Bayer HealthCare LLC	OLD	
870.7200	General Safety Evaluation for Topical Use of Imidacloprid (Advantage) Spot-On on Puppies: Lab Project Number: TR-96D-003: 74730: 10332. Unpublished study prepared by Bayer Corp. 47 p.	44099801	Bayer HealthCare LLC	OLD	
870.7200	Acute Oral Toxicity Evaluation of Imidacloprid (Advantage) in Dogs: Lab Project Number: TR-96D-010: 74764: J:USERS\LINDA\NOREPORT\JAS0171.RPT. Unpublished study prepared by Bayer Corp., Animal Health. 10 p.	44179801	Bayer HealthCare LLC	OLD	
Product Performance Test Guidelines					
810.3300	Efficacy Evaluation of Bay t 7391 (Imidacloprid) 10% Solution Applied Dermally for Control of Fleas on Dogs: Lab Project Number: 74572. Unpublished study prepared by AgResearch Consultants, Inc. 35 p.	43679609	Bayer HealthCare LLC	OLD	
810.3300	Efficacy Confirmation of NTN 33893 (Imidacloprid) Solution Applied Dermally for Control of Fleas on Dogs: Lab Project Number: 74541: MID 194. Unpublished study prepared by AgResearch Consultants, Inc. 15 p.	43679610	Bayer HealthCare LLC	OLD	
Signature 		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date December 19, 2014	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: December 19, 2014		EPA Reg No./File Symbol: 2517-NEW		Page 3 of 3	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® 9.1% Imidacloprid Squeeze On for Dogs			
Ingredient: Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Comparative Evaluation of How Quickly Advantage and Frontline (Fipronil) Top Spot Kill Fleas on Dogs: (final Report): Lab Project Number: 74800: PLRS 9665: 150.341. Unpublished study prepared by Professional Laboratory & Research Services, Inc. 51 p.	44256901	Bayer HealthCare LLC	OLD	
810.3300	Imidacloprid Topical Formulation: Larvicidal Effect Against Ctenocephalides felis in the Surroundings of Treated Dogs: (Revised Report): Lab Project Number: 74828: 97REPORT/ARTHER/HOPKINS.DOC. Unpublished study prepared by Bahrs Hill Research Station. 14 p.	44256902	Bayer HealthCare LLC	OLD	
810.3300	Evaluation of the Effects of Shampooing or Water Immersion on the Initial and Residual Efficacy of Advantage for Flea Control on Dogs: Lab Project Number: BD#296: 150.353: BD 296.Unpublished study prepared by AgResearch Consultants, Inc. 27 p.	44256903	Bayer HealthCare LLC	OLD	
Signature 		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date December 19, 2014	

Kumar, Rita

From: James Messina <jmessina@exponent.com>
Sent: Thursday, December 10, 2015 5:31 PM
To: Eagle, Venus; Kumar, Rita
Cc: Kelly Hoskins (Kelly.Hoskins@perrigo.com); Carrie Daniels
Subject: 2517-RTU and 2517-RTG

Dear Venus and Rita,

On behalf of my client, Sergeant's Pet Care Products, Inc., we are requesting that EPA move into the additional 30-day timeframe in compliance with EPA's Predecisional letter for 2517-RTU and 2517-RTG to allow us to work with EPA to resolve the remaining label comments. We understand that EPA will have addressed its PRIA requirements with regard to the due date and that the additional 30 days will be used to resolve the remaining label issues and for EPA to issue the EPA stamped approved labels.

We have received EPA's label comments and will work to submit revised labels early next week in hopes that they will be acceptable to EPA.

Please let me know if you have any questions or need any additional information. It is our clients intent to resolve the label issues and obtain the EPA approvals in as timely manner as possible.

Best Regards,

James Messina
Center Director and Principal Regulatory Consultant
Exponent[®], Inc | Center for Chemical Regulation and Food Safety
1150 Connecticut Ave., NW, Suite 1100
Washington, DC, United States of America
p: 202-772-4932 | c: 301-908-1181 | f: 202-772-4979
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Kumar, Rita

From: Kumar, Rita
Sent: Thursday, December 10, 2015 3:40 PM
To: 'James Messina'
Cc: Eagle, Venus; Carrie Daniels; Kelly Hoskins (Kelly.Hoskins@perrigo.com)
Subject: RE: 2517-RTU

Dear Jim: We have your response. All the comments listed in the attachment to Agency's pre-decisional letter dated 12/4/2015 have not been resolved. Please see our comments below, and refer to the 12/4/2015 attachment for comment numbers:

1. Okay.
2. Okay.
3. Not resolved. Upon discussion with our scientist, the data you cited (MRID number 4409801) only supports a minimum weight of 4.0 pounds. This change must be made on the across the board, as part of product name, and anywhere else where minimum age is mentioned (in marketing statements and/or directions for use). In addition, the minimum age must be qualified with "of age" or "old". All of these age descriptors cannot be optional.
4. Not resolved. The options for referral statement list insert. You must provide a referral statement if Directions for Use are in the insert.
5. Okay.
6. Okay.
7. Okay.
8. Not resolved. "same" is not acceptable, as indicated to you previously.
9. Not resolved. The asterisks and repeated listing of Bayer'sr products is too confusing. Write out what you want to convey, and delete redundant text.
10. . Resolved.
11. Resolved.
12. Not resolved. Revise the precautionary statements as required by the Agency. We will contact Bayer to make the same revision.
13. In the restrictions, revise minimum weight to 4 pounds.
14. Partially resolved. See below:
 - Bullet no. 7 must be revised to read: "Kills fleas within 12 hours, continues to kill for upto 4 weeks".
 - Two last but one flea bullets on your label revised 12/10/2015, must specify dogs over 7 weeks of age and 4 pounds
 - On the same label, last flea bullet must state "....prevents further flea infestations....."
 - On the same label, other bullets, first two bullets must specify min wt. This applies to any of the other marketing statements.
 - Delete the first X applications X weeks supply line. It is overly broad. The rest must specify 1 tube equals 1 dose 4 weeks supply 1 month supply, 2 tubes equal 2 doses 8 weeks supply etc.
 - bullets starting with for small dogs, for medium dogs etc. must be qualified with "For use ONLY on small dogs..." etc.
 - Last but third bullet does not make sense. What does clean cut open...mean?
 - Delete the bullet "Best if used year round".
15. See above under #14.
16. Resolved.
17. Resolved.
18. Resolved.
19. Resolved.

20. Not resolved. For clarity and consistency, place the Storage and Disposal statement inside a solid line box.
21. Resolved.
22. Not resolved. Delete the graphics that we objected to.
23. Not resolved. Delete the graphics that we objected to.
24. Not resolved. Delete the graphics that we objected to.
25. Resolved,

Additional comments: On your last label dated 12/10/2015, As indicated to you earlier, The How to Apply directions on page 8 of 11 are inconsistent with page 10 optional package copy or insert. Make these consistent or delete. We prefer the number and bullet format for How to apply, it is much clearer for the user.

These comments also apply to the cat product (2517-RTG), except for the minimum weight issue. You will receive a detailed list for RTG tomorrow.

Regards,
Rita

From: James Messina [mailto:jmessina@exponent.com]
Sent: Thursday, December 10, 2015 9:57 AM
To: Kumar, Rita <Kumar.Rita@epa.gov>
Cc: Eagle, Venus <Eagle.Venus@epa.gov>; Carrie Daniels <cdaniels@exponent.com>; Kelly Hoskins (Kelly.Hoskins@perrigo.com) <Kelly.Hoskins@perrigo.com>
Subject: 2517-RTU

Dear Rita,

Thank you again for reviewing the label comment response for 2517-RTU so quickly. Please find attached an updated label (track changes and clean versions).

The following provides feedback on the few outstanding issues related to EPA's additional comments below:

3. This issue needs to be discussed more with our scientists.

Sergeant's Response: This product is a generic product that is substantially similar to EPA approved basic registrations with EPA registration numbers 11556-117, 11556-119, 11556-120 and 11556-122. Sergeant's has modeled their generic product after the basics, including the proposed product label. The pending product has been supported by citing the basic registrations' data (i.e., acute toxicity, companion animal safety, and efficacy); therefore, the proposed product label should be identical or substantially similar to the basic registration labels. This includes the minimum weight for the smallest dog product.

The Bayer Animal Health (BAH) EPA stamped approved label (EPA Registration Number 11556-117, small dogs) dated August 29, 2012 (see attached highlighted copy) relies upon the same companion animal safety data Sergeant's has cited (MRID 44099801) and includes the following language:

- **"For use only on dogs and puppies 7 weeks and older and weighing 3½ to 10 lbs." (page 2 of 8)**
- **"Do not apply to puppies or dogs weighing less than 3½ lbs." (page 4 of 8)**
- **"For external use only on dogs and puppies 7 weeks and older and weighing 3½ to 10 lbs." (page 8 of 8)**

Based upon a review of the publicly-available EPA documents, the BAH product (EPA Reg. No. 11556-117) and the other EPA approved BAH imidacloprid dog products (the only difference is the dose sizes) were initially registered by EPA with a 7-week age restriction on puppies. At that time, no minimum weight was required by EPA to be placed on the label. These same data, BAH Report 74730, EPA MRID 44099801, are cited in Sergeant's data matrix. Subsequently, when EPA required minimum weight restrictions (the Agency's September 30, 2011 letter), BAH submitted new labeling with a 3½ lbs. weight restriction based on these same data. The Agency reviewed this submission and accepted the 3½ lbs. minimum weight restriction as part of the mitigation revisions (EPA stamped approved label dated August 29, 2012). This is the current minimum weight restriction on the EPA stamped approved BAH labels. Therefore, Sergeant's label should also include the EPA approved minimum weight of 3½ lbs.

Please let us know how EPA wants to proceed on this label claim as it is important for Sergeant's to have the same minimum dog weight as BAH.

4. Your response is partially acceptable. You may indicate full precautionary statements on the side or back panels. However, the human hazard statements must be indicated on the package itself. And the First Aid box must be placed above the Precautionary Statements. Additionally, the signal word "Warning" must be placed at the beginning of the paragraph, before "Hazards to Humans", and it must be in a larger size font for prominence.

Sergeant's Response: We have reviewed the label regulations at 40 CFR 156.10 and the LRM and do not see the requirement to place the first aid box above the precautionary statements. Further, we have checked several EPA stamped approved labels (11556-116 and others) and there appears to be no consistency with location of first aid above the precautionary statements. During our review we have noted that many products have the first aid on the inside panel or on the insert inside of the box. We believe this is due to the fact that there are numerous label language requirements to be placed on a limited space label/package. Please note we are not proposing this for our label, but merely pointing it out to EPA. Based upon our research, we have left the location as is on the updated label. We checked the updated label and the signal word (warning) follows the heading Hazards to Humans and is before the actual text. This is consistent with the LRM and several EPA stamped approved labels (11556-116, 2596-183 and others). We have left the location as is on the updated label.

7. Your response is acceptable, but we have been asking all registrants to place Storage and Disposal statements inside a solid line box, and suggest that you follow the same format for consistency.

Sergeant's Response: At this time, Sergeant's chooses not to include a solid line box. It will ensure that the Storage and Disposal directions are clear and understandable.

8. Your response is not acceptable. You must delete the optional word "[same]" from: "Contains imidacloprid, the same active ingredient used in....." or any similar statements. This implies comparison, which is not allowed.

Sergeant's Response: We have complied with EPA requirements to delete any comparative language; however, we believe the use of the word "same" is factually correct. The active ingredient in this product is imidacloprid. It is sourced from EPA registered technical grade active ingredients (TGAI's) consisting of imidacloprid. By registering these TGAI's, EPA has determined that they all contain imidacloprid. Further, it is our understanding that all imidacloprid containing TGAI's have cited the same Bayer database. Therefore, Sergeant's product does contain the "same" active ingredient as the other registered imidacloprid containing end-use products. Again, we believe this is factually correct. We request that EPA allow us to maintain the word "same" on the product label.

10. Your response is not acceptable. Study in the cited MRID(44256902) does not support inclusion of this claim. As we wrote to you before, Bayer has been contacted regarding this issue. This claim in any for (“dog’s surroundings” or dog’s environment”) is not acceptable, and must be deleted.

Sergeant’s Response: It is our understanding that BAH is being required to remove this statement from its label. In good faith, Sergeant’s has agreed to remove it from the updated label.

11. Your response is acceptable, although this makes the label very confusing. The important text like precautionary statements and directions for use are not as clear and prominent as they should be.

Sergeant’s Response: It is our preference to maintain the optional marketing language in the current location on the updated label. Please note, that Sergeant’s will comply with the EPA labeling requirements on its FPL so that the required language is clear and prominent.

13. Your response is partially acceptable. There is one optional statement on page 9: “Do not reapply for four [4] weeks [30 days].” This statement is not optional, and it must be moved to Restrictions on page 6.

Sergeant’s Response: We have not moved this statement on this label. We have left it under Frequency of Application. The BAH stamped approved label (11556-117) states “In case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not retreat more often than once every seven days. After flea control is attained, return to a monthly retreatment schedule.” Based upon this EPA approved label language we believe it would be inconsistent and misleading to list this as a restriction on our label.

14. Your response is partially acceptable. Please see below:

- a. Bullet number 7 must be deleted. This statement in its entirety does not exist on the Bayer label (11556-117) that you cited. You may add “Kills fleas on dogs within 12 hours”, but not change this text.

Sergeant’s Response: It is our understanding that the statement does not have to exist in its entirety on the BAH label. The current BAH label (11556-116) states in separate claims: “One treatment prevents further flea infestations for a least four (4) weeks.” and “Kills fleas on dogs within 12 hours.” (noting this language is found elsewhere on the BAH label). By virtue of this product being approved as a 30 day flea treatment, it is factually correct (and supported by the BAH data) that it kills fleas for a minimum of 30 days (4 weeks/1 month). Therefore, we request to keep the statement “Kills fleas in 12 hours, continues to kill for 4 weeks.” This claims factually states the product kills in 12 hours and continues to work for 4 weeks.

- b. The last two bullets must be deleted. As indicated in #10 above, the claim about flea control in dog’s environment is not acceptable.

Sergeant’s Response: We have updated the label accordingly.

The claim: Best if applied year round” is not acceptable, there are no fleas in winter in many parts of the country.

Sergeant’s Response: We do not understand why the Agency has a concern about recommending that the end-user use this product every month of the year. While the label recommends a monthly use, it makes better sense to inform the end-user that using it for the full year will provide continued monthly protection. EPA notes that in many parts of the country fleas might not be present in winter. Please note this is a nationally registered product label. In the USA Fleas are a year around problem. VetMd websites states the following:

“For those of us with pets, we look forward to winter as a time of respite from the bugs that torment us and our pets. We look forward to a break from the sprays and gels and powders and medicines ... all the things we try on our pets and in our home to keep the blood suckers at bay.

However -- and we hope you are sitting down as you read this -- winter does not necessarily spell the end of bug season. Consider the following ...

A New Housemate: Fleas and Ticks

The flea is a very persistent and resilient pest with a very complicated life cycle. It is even capable of surviving in outdoor temperatures as low as the upper 30s. As long as an adult flea can find a suitable host to feed from (such as wild animals or your pet), it can stay warm and healthy through the cold season. Their pupae remain settled in their cocoons until it is warm enough to come out -- as long as they have been placed in a location where they are protected from freezing cold (for example, a garage, covered patio, or basement).

Flea pupae can remain dormant for over a year until the surroundings have reached ideal temperatures. Once conditions are ideal (either inside or outside), the pupae will complete their development and emerge from their cocoons en masse, resulting in a surge of activity both on and off your pets.

Generally speaking, 65-80 degrees Fahrenheit with 75-85 percent humidity is the ideal temperature range for growth and reproduction of fleas. All they need is a warm place in which to settle and lay their eggs. For the majority of pet owners who keep their homes at a consistently warm temperature throughout the winter season, this can mean that a flea population, once settled indoors, can remain active all year long.

For residents of the southern states of the U.S., where the winter season may only go as low as the 30s, fleas will often stay active throughout most or all of the winter season. Only sustained cold (less than 30 degrees) and low humidity levels will kill off outdoor eggs, larvae, and adult fleas.

The best time to fight fleas is during the winter, when there is the best chance that they will become less active and fewer in number. Regularly vacuuming the areas where your pet spends time and continuing regular flea treatments throughout the winter season are the best ways to combat them before the next flea season is in full swing.”

http://www.petmd.com/dog/seasonal/evr_multi_flea_tick_mosquito_care_during_winter

Based upon the above information, we request to keep this statement on the label.

15. Your response is partially acceptable. Please see below:

- a. Bullet number 4 relating xx number of applications to xx weeks supply will be more clear if you changed “applications” to a descriptor term for the applicator (tube, vial, pipette etc.).
- b. Bullet # 5: The word specially indicates this formulation is unique for dogs, which is not true. Therefore “specially” must be deleted.
- c. Last bullet “The only monthly flea protection you need for your dogs” is not acceptable. Delete this or change as follows: “The only monthly flea protection you need for your dog when applied monthly.”

Sergeant’s Response: We have updated the label accordingly.

17. Your response is not acceptable. You must revise this statement to read as follows: “This product kills fleas on dogs within 12 hours”.

Sergeant’s Response: Please refer to #14 above.

21. Your response is partially acceptable. Similar change is needed on page 8 under How to Apply.

Sergeant’s Response: Please refer to #8 above.

22. Your response is partially acceptable. The following graphics are not acceptable:

a. Graphic and text related to flea larvae. This claim is not supported.

Sergeant's Response: We have updated the label accordingly.

b. Graphic with the text: Satisfaction Guaranteed. This must be qualified with "or your money back".

Sergeant's Response: Sergeant's label includes a Good Housekeeping icon and a Satisfaction Guaranteed icon. These icons do not have any FIFRA implications nor are they regulated under FIFRA. The EPA Label Review Manual states the following

"The following graphics and symbols are considered acceptable and may be ignored during, and are not part of, the label review. 1. The "Good Housekeeping Seal of Approval" is a limited warranty to consumers and promises to refund the purchase price or replace the product if defective. While the Agency allows this symbol to be placed on products, the agency does not endorse the warranty message provided by this symbol."

Further, the Satisfaction Guaranteed icon is a general statement notifying the end-user that their use of this product will be backed by the seller to ensure their satisfaction with the product. This is part of Sergeant's product stewardship program. The manner in which Sergeant's responds to a customer related to possible dissatisfaction with the purchase and/or use of the product is at Sergeant's discretion.

We have also reviewed the LRM (Chapter 12) and do not see any EPA requirements that do not allow the statement/graphic "Satisfaction Guaranteed". The LRM discusses the following types of statements that should be assessed on a case-by-case basis: 1. Over broad statements negating or detracting from the Directions for Use or other label language... 2. Label language asserting that the buyer has accepted the manufacturer's statement of his/her respective rights... 3. Overly broad language implying buyer has no legal right to recover damages from manufacturer... The proposed statement is not false and/or misleading, nor does it negate or detract from Directions for Use, nor does it waive any respective rights. In fact, the proposed statement is just the opposite in that it guarantees the satisfaction of the user/purchaser. Sergeant's requests to keep this statement on the label.

c. Picture of dog where application starts in the middle of back and goes up to the neck. This is opposite of what the use directions under the How to Apply.

Sergeant's Response: The label reflects directions for us that allow for application as a single spot or as a line (from middle of dogs' back to neck) and the text has been updated.

d. Made in the USA. This is not a true statement for all alternate formulations, and is misleading.

Sergeant's Response: The attached label includes two icons related to Made in the USA:

- **Made in the USA**
- **Made in the USA With Global Materials**

Both icons do not have any FIFRA implications nor are they regulated under FIFRA. These statements are regulated and enforced by the Federal Trade Commission (FTC). Sergeant's FPL will be in compliance with the FTC with regards to the U.S. Origin Claims by using the appropriate icon based upon the source of product ingredients; therefore, it will not be misleading. Sergeant's requests to keep this language and graphics on the label.

1. On page 1, for different size dogs, the package size must be mentioned (like 0.4 ml, 1.0 ml, 2.5 ml, 4.0 ml), to associate with corresponding size and weight of dog. An example is: For use ONLY on dogs weighing 3.5 to 10 lbs and over 7 weeks (0.4 ml size package). **[Updated on label to reflect as informational text for the reviewer]**
2. The cat icon on page 7 needs to be bigger, and moved to the right side of page. **[Updated on label]**
3. The How to Apply instructions on page 8 are confusing. For clarity and consistency, replace these with step by step and bulleted instructions on page 10.

Sergeant's Response: The Directions for Use found on this product label are identical in format to all EPA approved spot-on products under Sergeant's. The language has been used for 15+ years without any issues with EPA or confusion in the marketplace. Sergeant's has not received any consumer complaints about the Directions for Use.

The text under How to Apply is a summary of the detailed Directions for Use. This language is presented in a paragraph format and a numbered format. Again this language is on all of Sergeant's EPA approved spot-on products. We have not had any issues or comments from EPA with regards to this text. The language in question is found on all Sergeant's spot-on EPA approved labels. For consistency purposes and to avoid any confusion in the marketplace, we are unable to revise this text.

4. On page 10, Under How to Apply, you are referring to a label icon. Explain what label icon this is, or provide the graphic here. **[Deleted on label]**
5. On page 12, explain what label code are you referring to. **[Updated on label. Note this is an internal Sergeant's product number for tracking purposes. It is unique to the product.]**

Please review the attached updated product label for 2517-RTU and let me know if the EPA has additional comments. Please also let me know how the Agency plans to address #3 above with regards to timing.

Thank you again for your hard work on this label and turning it around so quickly. We look forward to working with you to try to finalize it.

Please contact me with any questions.

Best Regards,

James Messina

Center Director and Principal Regulatory Consultant

Exponent[®], Inc | Center for Chemical Regulation and Food Safety

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From: Kumar, Rita
Sent: Wednesday, December 09, 2015 5:43 PM
To: 'Carrie Daniels'
Cc: Kelly Hoskins (Kelly.Hoskins@perrigo.com); James Messina; Eagle, Venus
Subject: RE: 2517-RTU Response

Importance: High

Dear Carrie: Thanks you for the revised labels, and comments/justification on the comments included in attachment to the pre-decisional letter. You have not complied with the changes that we asked you to make in our letter dated December 4, 2015. Please see details below, the numbers relate to the label comments attachment that was sent to you with this attachment:

1. Your response is acceptable.
2. Your response is acceptable.
3. This issue needs to be discussed more with our scientists.
4. Your response is partially acceptable. You may indicate full precautionary statements on the side or back panels. However, the human hazard statements must be indicated on the package itself. And the First Aid box must be placed above the Precautionary Statements. Additionally, the signal word "Warning" must be placed at the beginning of the paragraph, before "Hazards to Humans", and it must be in a larger size font for prominence.
5. Your response is acceptable.
6. Your response is acceptable.
7. Your response is acceptable, but we have been asking all registrants to place Storage and Disposal statements inside a solid line box, and suggest that you follow the same format for consistency.
8. Your response is not acceptable. You must delete the optional word "[same]" from: "Contains imidacloprid, the same active ingredient used in....." or any similar statements. This implies comparison, which is not allowed.
9. Your response is acceptable.
10. Your response is not acceptable. Study in the cited MRID(44256902) does not support inclusion of this claim. As we wrote to you before, Bayer has been contacted regarding this issue. This claim in any for ("dog's surroundings" or dog's environment") is not acceptable, and must be deleted.
11. Your response is acceptable, although this makes the label very confusing. The important text like precautionary statements and directions for use are not as clear and prominent as they should be.
12. Your response is acceptable.
13. 13. Your response is partially acceptable. There is one optional statement on page 9: "Do not reapply for four [4] weeks [30 days]." This statement is not optional, and it must be moved to Restrictions on page 6.
14. Your response is partially acceptable. Please see below:
 - a. Bullet number 7 must be deleted. This statement in its entirety does not exist on the Bayer label (11556-117) that you cited. You may add "Kills fleas on dogs within 12 hours", but not change this text.
 - b. The last two bullets must be deleted. As indicated in #10 above, the claim about flea control in dog's environment is not acceptable. The claim: Best if applied year round" is not acceptable, there are no fleas in winter in many parts of the country.
15. Your response is partially acceptable. Please see below:
 - a. Bullet number 4 relating xx number of applications to xx weeks supply will be more clear if you changed "applications" to a descriptor term for the applicator (tube, vial, pipette etc.).

- b. Bullet # 5: The word specially indicates this formulation is unique for dogs, which is not true. Therefore "specially" must be deleted.
- c. Last bullet "The only monthly flea protection you need for your dogs" is not acceptable. Delete this or change as follows: "The only monthly flea protection you need for your dog when applied monthly."
- 16. Your response is acceptable.
- 17. Your response is not acceptable. You must revise this statement to read as follows: "This product kills fleas on dogs within 12 hours".
- 18. Your response is acceptable.
- 19. Your response is acceptable.
- 20. Your response is acceptable.
- 21. Your response is partially acceptable. Similar change is needed on page 8 under How to Apply.
- 22. Your response is partially acceptable. The following graphics are not acceptable:
 - a. Graphic and text related to flea larvae. This claim is not supported.
 - b. Graphic with the text: Satisfaction Guaranteed. This must be qualified with "or your money back".
 - c. Picture of dog where application starts in the middle of back and goes up to the neck. This is opposite of what the use directions under the How to Apply.
 - d. Made in the USA. This is not a true statement for all alternate formulations, and is misleading.

In addition we have noted the following on the revised label that you submitted:

- 1. On page 1, for different size dogs, the package size must be mentioned (like 0.4 ml, 1.0 ml, 2.5 ml, 4.0 ml), to associate with corresponding size and weight of dog. An example is: For use ONLY on dogs weighing 3.5 to 10 lbs and over 7 weeks (0.4 ml size package).
- 2. The cat icon on page 7 needs to be bigger, and moved to the right side of page.
- 3. The How to Apply instructions on page 8 are confusing. For clarity and consistency, replace these with step by step and bulleted instructions on page 10.
- 4. On page 10, Under How to Apply, you are referring to a label icon. Explain what label icon this is, or provide the graphic here.
- 5. On page 12, explain what label code are you referring to.

Please submit revised labeling ASAP.

Thanks,

Rita

From: Carrie Daniels [mailto:cdaniels@exponent.com]

Sent: Tuesday, December 08, 2015 12:07 PM

To: Kumar, Rita <Kumar.Rita@epa.gov>; Eagle, Venus <Eagle.Venus@epa.gov>

Cc: Kelly Hoskins (Kelly.Hoskins@perrigo.com) <Kelly.Hoskins@perrigo.com>; James Messina <jmessina@exponent.com>

Subject: 2517-RTU Response

Dear Rita and Venus,

Please find attached Sergeant's response for 2517-RTU. It is our understanding that EPA will process the email submission. Please let me know if EPA requires a copy to be submitted to document processing.

Please let me know if you have any questions or need any additional information. Jim will be out of the office at an EPA meeting this afternoon but should be available after 3:00 pm. In his absence, please contact me at 202-772-4916. Thank you in advance for your time and efforts.

Best Regards,
Carrie Daniels

Senior Managing Regulatory Consultant
Exponent, Inc.
202-772-4916

Kumar, Rita

From: James Messina <jmessina@exponent.com>
Sent: Thursday, December 10, 2015 5:31 PM
To: Eagle, Venus; Kumar, Rita
Cc: Kelly Hoskins (Kelly.Hoskins@perrigo.com); Carrie Daniels
Subject: 2517-RTU and 2517-RTG

Dear Venus and Rita,

On behalf of my client, Sergeant's Pet Care Products, Inc., we are requesting that EPA move into the additional 30-day timeframe in compliance with EPA's Predecisional letter for 2517-RTU and 2517-RTG to allow us to work with EPA to resolve the remaining label comments. We understand that EPA will have addressed its PRIA requirements with regard to the due date and that the additional 30 days will be used to resolve the remaining label issues and for EPA to issue the EPA stamped approved labels.

We have received EPA's label comments and will work to submit revised labels early next week in hopes that they will be acceptable to EPA.

Please let me know if you have any questions or need any additional information. It is our clients intent to resolve the label issues and obtain the EPA approvals in as timely manner as possible.

Best Regards,

James Messina
Center Director and Principal Regulatory Consultant
E^xponent[®], Inc | Center for Chemical Regulation and Food Safety
1150 Connecticut Ave., NW, Suite 1100
Washington, DC, United States of America
p: 202-772-4932 | c: 301-908-1181 | f: 202-772-4979
e: jmessina@exponent.com | web: www.exponent.com

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Kumar, Rita

Resubmission:
5978433

From: Carrie Daniels <cdaniels@exponent.com>
Sent: Tuesday, December 08, 2015 12:07 PM
To: Kumar, Rita; Eagle, Venus
Cc: Kelly Hoskins (Kelly.Hoskins@perrigo.com); James Messina
Subject: 2517-RTU Response
Attachments: 2517-RTU Response Letter 12-7-2015.pdf; 8570-1 Imid for Dogs.pdf; 2517-RTU Revised Label 12-7-15.pdf; 2517-RTU Revised Label 12-7-15 clean.pdf; EPA Reg No 11556-117 Highlighted.pdf; 8570-27 Imid for Dogs.pdf; 2517-RTU Label Comments 12-7-2015.pdf

Dear Rita and Venus,

Please find attached Sergeant's response for 2517-RTU. It is our understanding that EPA will process the email submission. Please let me know if EPA requires a copy to be submitted to document processing.

Please let me know if you have any questions or need any additional information. Jim will be out of the office at an EPA meeting this afternoon but should be available after 3:00 pm. In his absence, please contact me at 202-772-4916. Thank you in advance for your time and efforts.

Best Regards,
Carrie Daniels

Senior Managing Regulatory Consultant
Exponent, Inc.
202-772-4916



Exponent
1150 Connecticut Ave., NW
Suite 1100
Washington, DC 20036

telephone 202-772-4900
facsimile 202-772-4979
www.exponent.com

December 8, 2015

Venus Eagle
Product Manager 01
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

**Subject: Response to EPA PRIA Predecisional Letter for Sergeant's 9.1%
Imidacloprid Spot On for Dogs (EPA File Symbol 2517-RTU)
Decision Number 498903**

Dear Ms. Eagle:

On behalf of Exponent's client, Sergeant's Pet Care Products, Inc. (Sergeant's), Exponent is responding to EPA's PRIA Predecisional Letter for Sergeant's 9.1% Imidacloprid Spot On for Dogs (EPA File Symbol 2517-RTU) dated December 4, 2015. Sergeant's wants to work with EPA to complete this registration by the current PRIA due date of December 10, 2015. We request that EPA review our response and let us know if this is possible or if the Agency will require additional time under PRIA to review and respond.

Please find enclosed the following documents in support of this response:

- 8570-1 form;
- Updated product label (track changes and clean versions);
- Copy of EPA stamped approved label for EPA Reg. No. 11556-117 (highlighted to demonstrate EPA approved language); and
- Revised EPA Formulator's Exemption Form.

Sergeant's has reviewed EPA's label comments and has addressed each in the enclosed document. Based upon discussions with Ms. R. Kumar and Ms. M. Lewis our enclosed updated label and response document outline the following:

- EPA comments that have been addressed by updating the label
- Support language for those label claims that have not been included in the updated label

Please note that during our review of the Agency label comments on the Sergeant's 9.1% Imidacloprid Spot On for Dogs (EPA File Symbol 2517-RTU) and the Sergeant's 9.1% Imidacloprid Spot On for Cats (EPA File Symbol 2517-RTG), we noted label comments that

Venus Eagle
December 8, 2015
Page 2

were not consistent between the two labels. Based upon our review, we incorporated various label comments from each review to ensure consistency between the final labels.

If you have any questions regarding this submission, please contact me at jmessina@exponent.com or 202-772-4932.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Messina', with a long horizontal flourish extending to the right.

James Messina
Authorized Representative of
Sergeant's Pet Care Products, Inc.

Enclosures

cc: Rita Kumar, EPA
Marianne Lewis, EPA
Kelly Hoskins, Sergeant's
Carrie Daniels, Exponent



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

December 4, 2015

James B. Messina
Authorized Agent for
Sergeant's Pet Care Products, Inc.
c/o Exponent, Inc.
1150 Connecticut Avenue, NW
Suite 1100
Washington, DC, 20036

Subject: PRIA Predecisional letter – New product registration
Product Name: Sergeant's 9.1% Imidacloprid Spot On for Dogs
EPA File Symbol: 2517-RTU
Decision Number: 498903

Dear Mr. Messina:

The Agency has completed its review and assessment of your application pursuant to Section 33(b)(3) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended by the Pesticide Registration Improvement Extension Act of 2012. The Agency has made a pre-decisional determination that your application cannot be approved unless revisions are made to the draft label dated March 2, 2015. The necessary label changes are specified on the attached document.

Since there is limited time before the PRIA Decision Due Date expires, it is important to discuss any objections you have to these changes immediately and whether you will need to submit additional data for review. If these discussions determine that submitting data will be necessary, the PRIA decision due date may need to be renegotiated to allow sufficient time to address and resolve such differences. If the PRIA Decision Due Date is not renegotiated, and the label issues are not resolved before the PRIA Decision Due Date, the Agency will send a follow-up letter that will represent the Agency's decision to close out the PRIA decision review time. The follow-up letter will provide the following three options for continuing the review of the application:

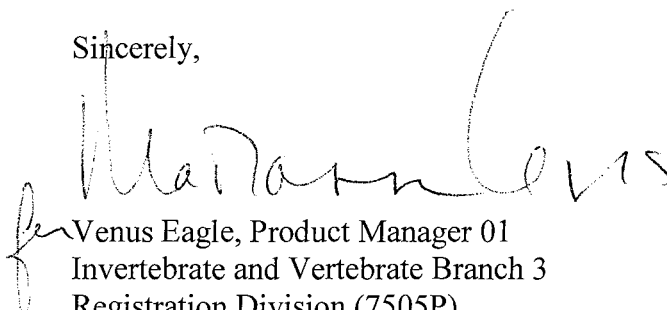
- a. You agree to all of the terms associated with the draft accepted label as revised by the Agency and request that it be issued as the accepted final Agency-stamped label; or
- b. You do not agree to one or more of the terms of the draft accepted label as revised by the Agency and request additional time to resolve the difference(s); or
- c. You withdraw the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee.

If you inform EPA that you have concerns as described under (b) above, you will have up to 30 calendar days from the date of that follow-up letter to reach agreement with the Agency on the final version of the label that the Agency will accept. If an agreement cannot be reached within those 30 days, EPA would intend to proceed with denial of the application.

If you agree to all of the terms of the accepted label as described in (a) above, or if you and EPA resolve any differences as described in (b), you must submit a revised label to EPA. EPA will then provide an accepted final Agency stamped label to you within 2 business days following your written electronic confirmation of agreement to the Agency including the revised label to be stamped.

If you have any questions, please contact Rita Kumar at kumar.rita@epa.gov or (703) 308-8291.

Sincerely,



Venus Eagle, Product Manager 01
Invertebrate and Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs

Attachment (1)

Attachment for Predecisional letter for 2517-RTU

Label Comments for 2517-RTU (Sergeant's 9.1% Imidacloprid Squeeze On for Dogs)

1. Alternate Confidential Statement of Formula #3 is not acceptable, because the source product is much different from source product in the basic formulation. Submit a revised Formulator's Exemption statement deleting the source product given in alternate formulation #3.
2. Indicate intended use(s) on the front panel, below product name.
3. Across the board, change minimum weight of dog/puppy from 3.5 lbs to 4 lbs based on the efficacy review.
4. On page 2, the referral statement for additional precautionary statements cannot be optional. Remove brackets from the entire statement. As per the 2011 pet spot-on mitigation revise "...]] for Additional Precautionary Statements]" to read "...]] for First Aid, Precautionary Statements, and Directions for Use."
5. Clearly indicate which text appears on front, back or side panels per the 2011 pet spot-on mitigation.
6. All cat icons must be in yellow and black color, and appear in lower right hand corner on the front panel in compliance with 2011 pet spot on mitigation letter sent to all registrants of such products.
7. On page 11, place the Storage and Disposal statement inside a solid line box for clarity and consistency.
8. On page 3 and elsewhere, remove statements such as "Compare to....." In reference to other companies products. Only include factual, non-comparative statements such as "Contains the active ingredient used in"
9. On page 3 and elsewhere, delete *, [* or [*]. These asterisks do not refer to any footnotes. The asterisk may not be used as a placeholder for other unspecified products as the Agency must verify that any listed product(s) contain the same a.i. at the same percentage
10. Delete the claim "Kills flea larvae in treated dog's surroundings [following contact with treated dog]". Efficacy data is required to support this claim. Bayer has been contacted to remove this claim from similar labels.
11. Please move any marketing claims to the end of the draft label (prior to the optional graphics) for better clarity in the label.
12. On page 5 in the "Precautionary Statements" revise "Wash hands thoroughly with soap and warm water after handling." to read "Wash hands after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet."
13. Under the Directions for Use, add a separate heading "Restrictions:" and place all the "Do not" statements under this separate heading "Restrictions".
14. Delete the following "Fleas" marketing claims:
 - Complete flea protection
 - Complete flea control
 - Optimal flea control
 - Optimal flea protection
 - Advanced flea protection

- Advanced flea control
 - Kills fleas in 12 hours, continues to kill for 4 weeks
 - Controls problems associated with fleas
 - Original vet strength
 - Fast acting
 - Waterproof
 - Remains effective even after shampooing, swimming, or exposure to sunlight [and][or][rain]
 - Remains effective, even after bathing, water immersion, or exposure to [sunlight][and][or][rain]
 - Delete brackets from “further” in statements such as: Prevents [further] flea infestation for four months.....” An acceptable claim would be written as follows: “Prevents further flea infestation for up to four weeks with one treatment.”
 - Kills flea larvae in dog’s environment following contact with treated dog. This claim would require efficacy data.
 - Best if used year round!
15. Delete the following “Other” marketing claims:
 - For dogs (this statement is too broad and unspecific)
 - Original Vet Strength (this is false and misleading, this or a similar formulation has been in the market for many years)
 - Fast acting, long acting (these are enhanced efficacy claims, must be supported by efficacy data and specific length of time)
 - All claims relating xx number of applications to xx weeks supply (these do not match the once a month application direction)
 - Delete “Specially” from “Specially formulated....” Statements
 - Change “Can be used” to “Use only on puppies over 7 weeks....”
 - The only flea protection you need for your dogs (or qualify this by adding “...when applied monthly [every 30 days])
 16. On page 5, under precautionary Statements, place “Do not get in eyes or on clothing” after all the hazard statements. Change Harmful if swallowed to read, “Harmful if swallowed. Harmful if absorbed through the skin.”
 17. On page 5, in the claims directly above “Read Entire label before each use” as per the efficacy review delete “This product kills fleas within 12 hours”
 18. On page 6, the header “Directions for Use” must be in a larger font and more prominent (e.g., underlined) to ensure that it is clear to user that everything that follows falls under this heading.
 19. On page 6, as per the 2011 pet spot-on mitigation (Section III, A, 1.,d) move the Cat Icon to the right hand side of the page.
 20. On page 8, place the Storage and Disposal statement inside a solid line box.
 21. On page 9, in the instructions for use paragraphs, remove brackets from all “Do not...” statements. These are restrictions and cannot be optional statements. Similarly, all of the use instructions cannot be optional, remove brackets from the first bracketed word, i.e., Invert tube [vial]..... etc.

22. On page 10, some of the optional graphics listed are mandatory, like the cat icon with slash thru, pictures of dog being treated, and the two graphics of how to apply. These must be included in the Directions for Use to illustrate the use of this product.
23. Delete the icon Satisfaction Guaranteed, or qualify it with "or your money back".
24. Delete the icon Made in the USA since the alternate source [REDACTED]
25. Per the implementation of label changes to pet spot on products in 2011:
 - a. The Front Panel is to have a large clear picture of a dog in the weight range for the product as packaged;
 - b. The Back Panel: Place the box labeled "Side Effects" at the lower right hand corner of the back panel.

Product ingredient source information may be entitled to confidential treatment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Rita Kumar

From: Jacquelyn Marchese, Entomologist

Jacquelyn Marchese

Secondary Review: Kevin Sweeney, Senior Entomologist

Kevin J. Sweeney

Date: November 12, 2015

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD (DER)

~~THIS DER DOES CONTAIN CONFIDENTIAL BUSINESS INFORMATION - DO NOT RELEASE TO REGISTRANT~~

Note: MRIDs found to be **unacceptable** to support label claims should be removed from the data matrix.

DP barcode: 427063

Decision no.: 498903

Submission no: 962069

Action code: R315

Product Name: RTU Sergeant's 9.1% Imidacloprid Squeeze on for Dogs

EPA Reg. No or File Symbol: 2517-RTU

Formulation Type: liquid

Ingredients statement from the label with PC codes included:

Imidacloprid 9.10% PC: 129099

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m² or mg/cm² or mg/kg body weight as appropriate):

Use Patterns:

Weight of dog (lb)	Amount of product (mL)	mL/kg of imidacloprid	Mg/kg of product	Mg/kg of imidacloprid
3.5-10	0.4 mL	0.008-0.023	97-277	8-25
11-20	1 mL	0.01-0.018	121-219	11-19
21-55	2.5 mL	0.009-0.02	108-283	9.8-25
55 +	4.0 mL	0.0146	108	9.8

*Based on 1.097 g/cm³ density

This product is to be applied to dogs over the age of 7 weeks, weighing over 3.5 lbs. The label directs the user to apply the product in three different ways:

- directly to the skin of the dog from the back of the neck to a point midway between the neck and tail
- as a spot on the dog's back between the shoulder blades
- as a stripe starting at the middle of the back and ending between the shoulder blades

I. Action Requested: This Sergeant's product was submitted as an R315, new end use, non-food animal product.

The proposed label has public health claims of kills fleas (eggs, larvae and adult), prevents flea egg hatch/development, stops the flea lifecycle, controls/kills fleas for up to 1 month, etc. The reviewer requested that the five submitted efficacy studies be reviewed to determine their applicability in support of the new product and the proposed label claims.

II. Background: The registrant has cited seven previously reviewed efficacy studies to support the registration of this new product and the claims against fleas.

III. MRID Summary:

43679609. Cunningham, J. 1995. Efficacy Evaluation of Bay t 7391 (Imidacloprid) 10% Solution Applied Dermally for control of Fleas on Dogs.

(1) GLP

(2) **Methods:**

On study day-3, 32 adult dogs of various breed, sex, and length of hair were initially infested with 100 fleas each to screen their ability to host the pest. On day -2, fleas were combed out and counted, and dogs were then separated into four groups of 8 dogs. Three out of the four groups were given Bay t 7391, a 10% imidacloprid solution, at various rates. Group 1 received the rate of 3.75 mg/kg, group 2 received 7.5 mg/kg, and group 3 received 10.0 mg/kg. The last group received a blank control substance. All treatments were administered with a syringe and was applied to the skin between the shoulder blades. Each dog was infested with approximately 100 adult fleas on days -1, 6, 13, 20, 27, and 33. Fleas were visually counted on days 1, 7, 14, 21, and 28 and were combed out and counted on day 34. Percent control was calculated by subtracting the number of fleas counted on the treated animals from the number of fleas counted on the control animals, divided by the number of fleas counted on the control animals.

(3) **Results:**

DAY	GROUP 1 3.75 mg/kg		GROUP 2 7.5 mg/kg		GROUP 3 10.0 mg/kg		GROUP 4 UNTREATED
	TOTAL	CONTROL	TOTAL	CONTROL	TOTAL	CONTROL	TOTAL
1	17	96.9	12	97.8	4	99.3	553
7	7	99.0	0	100	0	100	751
14	51	94.4	9	99.0	1	99.9	911
21	30	96.8	12	98.7	0	100	953
28	40	95.4	14	98.4	6	99.3	873
34	98	91.6	28	97.6	36	96.9	1171

(4) **Conclusion:** This study is **acceptable** and demonstrates that imidacloprid, when applied to dogs at the rate of 3.75 mg/kg, controls existing flea populations and continues to control fleas for up to 34 days.

MRID #. Title.

(1) GLP or non-GLP

(2) **Methods:** Include pests, application rate, use type (e.g., pet spot on, direct application, surface application, residual), type of spray (e.g., aerosol), replications and # individuals per replicate, L:D and/or surface type if applicable, exposure duration, and other important methods.

If there is a primary contractor review, it is not necessary to include the level of detail as described above. Instead,

you may just describe application rate, use type, type of spray, pests (1 to 2 sentences), and methods relevant to claims.

(3) **Results:** State the results for control and treatment groups.

(4) **Conclusion:** State whether the study is acceptable, partially acceptable, unacceptable, scientifically deficient, etc., as it will be entered in OPPIN. Provide the reasons for your conclusion (e.g., rate too high, inadequate control). List any pests supported by this study at the appropriate rates (for x time if residual).

43679610. Cunningham, J.; Everett, R.; 1994. Efficacy Confirmation of NTN 33893 (Imidacloprid) Solution Applied Dermally for Control of Fleas on Dogs.

(1) non-GLP

(2) **Methods:** Thirty-seven adult dogs of various breed and hair lengths were initially selected for the study. On day -2, dogs were infested with 100 male and female adult fleas. Fleas were combed out, counted, and removed on day -1. Thirty dogs (18 female, 12 male) were then chosen based on their ability to harbor fleas and were divided into 3 groups of 10. The first group received an 8.5% imidacloprid solution at the rate of 0.1 mL of imidacloprid/kg directly between the shoulder blades, the second group received a 5.0% imidacloprid solution 0.2 mL/kg of imidacloprid, half between the shoulder blades and half on the romp, and the third received a placebo on two unspecified locations. All treatments were received by applying the solution directly to the skin. Dogs were then infested with 100 fleas each on days 6, 13, 20, 27, and 34. Fleas were counted on days 1, 7, 14, 21, and 28, and were combed out and counted on days 35 and 42. Percent control was calculated using Abbott's formula, by subtracting the average number of fleas counted on the treated animal from the average number of fleas counted on the untreated animals divided by the average number of fleas counted on the untreated animal.

(3) **Results:**

Fleas

Total fleas and percent control of fleas were as follows:

<u>Day</u>	GROUP 3		GROUP 2		GROUP 1	
	Untreated		5% NTN		8.5% NTN	
	<u>Total</u>		<u>Total</u>	<u>Control</u>	<u>Total</u>	<u>Control</u>
1	494	0	100		0	100
7	632	0	100		2	99.7
14	728	27	96		13	98
21	806	19	98		20	98
28	676	40	94		22	97
35	1174	82	93		75	94
42	689	162	76		235	66

(4) **Conclusion:** This study is **unacceptable** because the tested rate of imidacloprid per kg of body weight is higher than the labeled rate of imidacloprid for this product.

44256901. Cruthers, L.; 1997. Comparative Evaluation of How Quickly Advantage and Frontline (Fipronil) Top Spot Kill Fleas on Dogs

(1) GLP

(2) **Methods:** Thirty adult, mix-breed dogs of both sexes were selected for the study. Dogs were separated into 3 groups of 10 (X, Y, or Z). On test day 0 each group received a different treatment. Members of group X received Advantage (9.1% Imidacloprid), group Y received Frontline Top Spot (9.7% fipronil) and members of Group Z

received the Advantage blank vehicle. The products were applied to the dogs per the labeled application rate. The application rate of Advantage mimicked the application rate of the proposed product (minimum of 0.008 mL/kg). On days -1, 6, 13, 20, and 27 dogs were infested with approximately 100 adult cat fleas. Two dogs from each group were examined and fleas were evaluated to be dead, alive or moribund on 2, 4, 8, 12, and 24 hours post treatment. All alive and moribund fleas were gathered and held in a separate container for 24 hours to determine mortality. Further, all fleas collected were dissected and evaluated for blood ingestion to determine if treatment prevented fleas from biting. Efficacy was calculated by subtracting the average number of fleas counted on the treated animal from the average number of fleas counted on the untreated animals divided by the average number of fleas counted on the untreated animal.

(3) Results:

BLOOD DETECTED IN THE BODIES OF DEAD FLEAS* TEST DAY 0

TIME INTERVAL	TREATMENT	TOTAL NO. DEAD FLEAS RECOVERED	NO. OF FLEAS WITH BLOOD	PERCENT POSITIVE FOR BLOOD
2 HRS	ADVANTAGE	10	6	60.0
	TOP SPOT	8	6	75.0
	CONTROL	0	0	-
4 HRS	ADVANTAGE	15	15	100
	TOP SPOT	5	2	40.0
	CONTROL	3	1	33.3
8 HRS	ADVANTAGE	151	101	66.9
	TOP SPOT	165	115	69.7
	CONTROL	0	0	-
12 HRS	ADVANTAGE	99	88	88.9
	TOP SPOT	140	93	66.4
	CONTROL	1	1	100
24 HRS	ADVANTAGE	145	99	68.3
	TOP SPOT	169	153	90.5
	CONTROL	12	12	100

* DEAD FLEAS RECOVERED FROM THE DOGS DURING COMBING OR FROM PANS BENEATH THE DOGS.

BLOOD DETECTED IN THE BODIES OF LIVE FLEAS*
TEST DAY 0

TIME INTERVAL	TREATMENT	TOTAL NO. LIVE FLEAS RECOVERED	NO. OF FLEAS WITH BLOOD	PERCENT POSITIVE FOR BLOOD
2 HRS	ADVANTAGE	130	78	60.0
	TOP SPOT	116	40	34.5
	CONTROL	179	137	76.5
4 HRS	ADVANTAGE	100	85	85.0
	TOP SPOT	112	38	33.9
	CONTROL	174	122	70.1
8 HRS	ADVANTAGE	22	20	90.9
	TOP SPOT	11	7	63.6
	CONTROL	195	103	52.8
12 HRS	ADVANTAGE	0	0	-
	TOP SPOT	0	0	-
	CONTROL	177	138	78.0
24 HRS	ADVANTAGE	0	0	-
	TOP SPOT	0	0	-
	CONTROL	180	142	78.9

* LIVE FLEAS RECOVERED FROM THE DOGS DURING COMBING AND HELD FOR 24 HOURS BEFORE EXAMINATION FOR BLOOD.

LIVE FLEAS RECOVERED FROM DOGS AND PERCENT FLEA CONTROL
TEST DAY 0

TIME INTERVAL	ADVANTAGE		TOP SPOT		CONTROL	
	DOG NO.	NO. LIVE FLEAS	DOG NO.	NO. LIVE FLEAS	DOG NO.	NO. LIVE FLEAS
2 HRS	6823	57	7775	52	18175	86
	15081	73	10825	64	11631	93
	MEAN	65.0	MEAN	58.0	MEAN	89.5
	% CONTROL	27.4	% CONTROL	35.2	% CONTROL	-
4 HRS	16012	66	17206	64	HIEMBY	84
	15025	34	18604	48	15161	90
	MEAN	50.0	MEAN	56.0	MEAN	87.0
	% CONTROL	42.5	% CONTROL	35.6	% CONTROL	-
8 HRS	11698	0	18336	2	17526	98
	16744	22	HHCAYJ	9	18561	97
	MEAN	11.0	MEAN	5.5	MEAN	97.5
	% CONTROL	88.7	% CONTROL	94.3	% CONTROL	-
12 HRS	EFGGG	0	18393	0	15783	87
	2863	0	HHFMRW	0	14802	90
	MEAN	0	MEAN	0	MEAN	88.5
	% CONTROL	100	% CONTROL	100	% CONTROL	-
24 HRS	15185	0	245	0	13995	100
	15737	0	HHFMRX	0	14368	80
	MEAN	0	MEAN	0	MEAN	90.0
	% CONTROL	100	% CONTROL	100	% CONTROL	-

BLOOD DETECTED IN THE BODIES OF DEAD FLEAS*
TEST DAY 27

TIME INTERVAL	TREATMENT	TOTAL NO. DEAD FLEAS RECOVERED	NO. OF FLEAS WITH BLOOD	PERCENT POSITIVE FOR BLOOD
2 HRS	ADVANTAGE	44	40	90.9
	TOP SPOT	14	11	78.6
	CONTROL	14	12	85.7
4 HRS	ADVANTAGE	87	63	72.4
	TOP SPOT	90	65	72.2
	CONTROL	7	5	71.4
8 HRS	ADVANTAGE	67	48	71.6
	TOP SPOT	74	56	75.7
	CONTROL	12	12	100
12 HRS	ADVANTAGE	72	44	61.1
	TOP SPOT	94	54	57.4
	CONTROL	7	3	42.9
24 HRS	ADVANTAGE	87	69	79.3
	TOP SPOT	59	45	76.3
	CONTROL	10	10	100

* DEAD FLEAS RECOVERED FROM THE DOGS DURING COMBING OR FROM PANS BENEATH THE DOGS.

BLOOD DETECTED IN THE BODIES OF LIVE FLEAS*
TEST DAY 27

TIME INTERVAL	TREATMENT	TOTAL NO. LIVE FLEAS RECOVERED	NO. OF FLEAS WITH BLOOD	PERCENT POSITIVE FOR BLOOD
2 HRS	ADVANTAGE	49	40	81.6
	TOP SPOT	65	30	46.1
	CONTROL	105	105	100
4 HRS	ADVANTAGE	2	2	100
	TOP SPOT	4	4	100
	CONTROL	128	91	71.1
8 HRS	ADVANTAGE	0	0	-
	TOP SPOT	3	2	66.7
	CONTROL	128	91	71.1
12 HRS	ADVANTAGE	17	14	82.3
	TOP SPOT	6	2	33.3
	CONTROL	92	89	96.7
24 HRS	ADVANTAGE	2	2	100
	TOP SPOT	3	3	100
	CONTROL	110	69	62.7

* LIVE FLEAS RECOVERED FROM THE DOGS DURING COMBING AND HELD FOR 24 HOURS BEFORE EXAMINATION FOR BLOOD.

**LIVE FLEAS RECOVERED FROM DOGS AND PERCENT FLEA CONTROL
TEST DAY 27**

TIME INTERVAL	ADVANTAGE		TOP SPOT		CONTROL	
	DOG NO.	NO. LIVE FLEAS	DOG NO.	NO. LIVE FLEAS	DOG NO.	NO. LIVE FLEAS
2 HRS	6823	4	7775	35	18175	64
	15081	45	10825	30	11631	41
	MEAN	24.5	MEAN	32.5	MEAN	52.5
	% CONTROL	53.3	% CONTROL	38.1	% CONTROL	-
4 HRS	16012	0	17206	0	HIEMBY	62
	15025	2	18604	4	15161	66
	MEAN	1.0	MEAN	2.0	MEAN	64.0
	% CONTROL	98.4	% CONTROL	96.9	% CONTROL	-
8 HRS	11698	0	18336	1	17526	67
	16744	0	HBCAVJ	2	18561	61
	MEAN	0	MEAN	1.5	MEAN	64.0
	% CONTROL	100	% CONTROL	97.7	% CONTROL	-
12 HRS	EFGMG	0	18393	0	15783	54
	2863	17	HBFMRW	6	14802	38
	MEAN	8.5	MEAN	3.0	MEAN	46.0
	% CONTROL	81.5	% CONTROL	93.5	% CONTROL	-
24 HRS	15185	2	245	1	13995	49
	15737	0	HBFMRX	2	14368	61
	MEAN	1.0	MEAN	1.5	MEAN	55.0
	% CONTROL	98.2	% CONTROL	97.3	% CONTROL	-

(4) **Conclusion:** This study is **partially acceptable**. The study supports that imidacloprid, when applied to a dog at 0.008 mL/kg kills fleas. The data do not support claims that imidacloprid prevents fleas from biting a dog. Also, time based claims are supported by showing statistical significance which is not prevented here and are thus not supported.

44256902. Hopkins, T.; Woodley, I.; Gyr, P.; 1997. Imidacloprid Topical Formulation: Larvicidal Effect Against *Ctenocephalides felis* in the Surroundings of Treated Dogs.

(1) non-GLP

(2) **Methods:** This MRID consists of two studies. The first study only tested 4 dogs, while the second study tested 7 dogs in 2 groups.

Entomologist's note: In order to receive meaningful statistical results from a study, the minimum number of dogs recommended to test in one group is 6. Therefore, these studies will not be considered due to insufficient replication and statistical power.

(3) **Results:** As too few test animals were studied in these tests, the results will not help support the subject product of this review.

(4) **Conclusion:** As stated above, this MRID is **unacceptable** because of too few replicates in the study design. No claims can be supported with this test.

44256903. Cunningham, J. 1997. Evaluation of the Effects of Shampooing or Water Immersion on the Initial and Residual Efficacy of Advantage for Flea Control on Dogs.

(1) GLP

(2) **Methods:** Twenty-four adult, mixed-breed dogs were randomly assigned to 3 groups. On day 0, groups 1 and 2 were treated with Advantage solution (9.1% imidacloprid), per label instructions. (Dogs in group 1 received an average imidacloprid dose of 16 mg/kg, and dogs in group 2 received an average imidacloprid dose of 14.5 mg/kg). Group 3 served as the control and received a placebo treatment. Imidacloprid treatment was administered depending on the weight of the dog. Dogs 20 pounds and under received the treatment between the shoulder blades, and dogs weighing 21 pounds and over received the treatment in 3-4 even spots along the back from the top of the shoulder to the base of the tail. Each dog was infested with 100 unfed adult fleas on days -1, 6, 13, 20, 27, and 34. Live fleas remaining on each dog were counted and removed on days 1, 7, 14, 21, 28, and 35. On day 4, group 1 dogs were shampooed with an emollient shampoo (Allegroom Virbac) and rinsed. Group 2 dogs were immersed in a tank of water for one minute. Half of group 3 dogs were shampooed and the other half were immersed in water. The water immersion treatment was repeated on the same dogs on days 11, 18, 25, and 32.

Percent control was calculated using Abbott's formula, by subtracting the average number of fleas counted on the treated animal from the average number of fleas counted on the untreated animals divided by the average number of fleas counted on the untreated animal.

(3) **Results:**

GROUP 1 - ADVANTAGE TREATMENT (DAY 0) FOLLOWED BY SHAMPOOING ON DAY 4

Dog No.	NUMBER FLEAS / DOG						
	DAY						
	-2	1	7	14	21	28	35
202	80	0	15	17	30	17	32
315	62	0	0	1	4	1	15
353	76	0	0	0	2	1	20
369	97	0	0	0	0	0	5
401	86	0	0	3	18	11	39
497	89	0	0	1	0	0	33
523	104	0	12	35	27	19	48
526	78	0	0	0	10	13	54
TOTAL	672	0	27	57	91	62	246
MEAN	84.0	0.0	3.4	7.1	11.4	7.8	30.8
% CONTROL	-	100	96.2	92.5	88.1	92.2	65.5

GROUP 2 - ADVANTAGE TREATMENT (DAY 0) FOLLOWED BY WATER IMMERSION ON DAYS 4, 11, 18, 25, 32

Dog No.	NUMBER FLEAS / DOG						
	DAY						
	-2	1	7	14	21	28	35
201	103	0	0	0	8	15	31
313	71	0	0	2	4	11	18
341	79	0	0	0	4	0	10
357	76	0	0	0	0	0	8
386	85	0	2	4	43	48	52
394	100	0	0	1	13	1	35
440	90	0	0	0	1	0	1
451	73	0	0	0	0	0	3
TOTAL	677	0	2	7	73	76	158
MEAN	84.6	0.0	0.3	0.9	9.1	9.5	19.8
% CONTROL	-	100	99.6	99.0	89.7	88.8	78.7

GROUP 3 - CONTROL - PLACEBO TREATMENT (DAY 0) FOLLOWED BY SHAMPOOING OR WATER IMMERSION.

DOG No.	NUMBER FLEAS / DOG						
	DAY						
	-2	1	7	14	21	28	35
228a	69	93	101	96	89	106	91
298a	86	103	96	101	96	104	96
442a	80	78	90	80	95	93	82
450a	108	106	75	103	103	99	88
Total	343	380	362	380	383	402	357
Mean	85.8	95.0	90.5	95.0	95.8	100.5	89.3
336b	78	74	76	93	82	95	83
368b	91	55	49	88	80	86	95
371b	71	58	91	63	85	68	90
383b	84	71	90	105	105	89	103
Total	324	268	306	349	352	338	371
Mean	81.0	67.0	76.5	87.3	88.0	84.5	92.8

a - Dogs shampooed on day 4.

b - Dogs immersed in water on days 4, 11, 18, 25, 32.

(4) **Conclusion:** This study is **unacceptable**, as imidacloprid is tested at a rate of 14.5 mg/kg which is higher than the minimum imidacloprid rate of 9.8 mg/kg on the label. Further, as the water immersion and shampooing test is not stringent enough. For a full shampooing claim, animals must be shampooed and rinsed for 5 minutes, while for a water-proof test only, dogs must be immersed for 1 minute.

IV. EXECUTIVE DATA SUMMARY:

(A) Sergeant's Imidacloprid Squeeze On for Dogs is a proposed dog spot-on product for the control of fleas. The product will be packaged and marketed to various sizes of dogs based on weight. The lowest labeled rate of active ingredient that will be marketed is proposed to be 8 mg/kg of imidacloprid. The combination of five studies submitted support that the product, when applied to dogs, is efficacious against adult and larval cat fleas.

V. LABEL RECOMMENDATIONS:

(1) No changes for the Directions for Use are suggested. Please note this section describes slight variations in application of the product to the dog. These variations will not affect the efficacy of the product against fleas.

(2) The following marketing claims are acceptable:

- Prevents [further] flea infestation for 1 month (or equivalent)
- Protects against further infestation
- Kills fleas and may reduce the incidence of hypersensitivity skin disorder called flea allergy dermatitis (FAD), which may be caused by the feeding activity of fleas on dogs.
- Apply monthly to control and prevent fleas
- Apply monthly for optimal flea control and to prevent fleas
- Continues to kill fleas for 4 weeks
- Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation
- Active against fleas
- Kills fleas on puppies and dogs
- Offers protection against fleas
- Flea control
- Protects against the infestation and reinfestation of the home by fleas on treated dogs

- Controls fleas which can serve as an intermediate tapeworm host
- Provides multi-stage flea control
- Kills flea larvae

(3) The following marketing claims are unacceptable:

- Kills fleas within 12 hours
- Kills reinfesting fleas within 2 hours
- Protects against irritating flea bites
- Kills adult fleas before they lay eggs
- Kills flea larvae in treated dog's surroundings [following contact with treated dog]
- Complete flea protection
- Optimal flea control
- Optimal flea protection
- Advanced flea protection
- Kills fleas in 12 hours
- Controls problems associated with fleas
- Original vet strength
- Fast acting
- Remains effective after exposure to sunlight
- Flea life cycle claims (especially graphic on page 10 of the label dated 3/2/2014).
- Waterproof
- Remains effective even after bathing, shampooing, water immersion, rain, swimming

~~CONFIDENTIAL APPENDIX - DO NOT RELEASE TO REGISTRANT~~

This product is a me-too of 11556-117, 11556-119, 11556-120, and 11556-122. As such, Sergeants cited 5 efficacy studies (reviewed in EPA review dated 5/5/1997). Although many of the MRIDs are now rated unacceptable to today's standards (see plains on page 15), the following me-too claims are allowed until the Agency calls in efficacy data for all dog products.

- Kills fleas within 12 hours
- Kills reinfesting fleas within 2 hours
- Kills adult fleas before they lay eggs
- Kills fleas in 12 hours
- Waterproof
- Remains effective even after bathing, shampooing, water immersion, rain, swimming
- Controls of larvae in areas frequented by treated pets

Kumar, Rita

From: Doug Spilker <doug.spilker@bayer.com>
Sent: Wednesday, November 04, 2015 9:41 AM
To: Kumar, Rita
Subject: RE: A question about 11556-116 (syn. 11556-RRA) and -117 (11556-RRT)
Attachments: Advantage products Acute Tox DER 3-5-1996..pdf

Dear Rita,

The registrations you are citing contain the "classic" formulation of Advantage (10% imidacloprid.)

Per 40 CFR 157.22, the results of the acute tox testing do not requirement the products be in Child Resistant Packaging (see attached DER), and therefore do not require that a certification letter be on file.

Best Regards,
Doug

Douglas A. Spilker, Ph.D.
Manager - EPA Reg. Affairs
BAYER HEALTHCARE LLC
Animal Health Division
Office: 913-268-2751
Mobile: 816-506-3102
Email: doug.spilker@bayer.com

Address:
P.O. Box 390
Shawnee Mission, KS 66201-0390
Country: USA



Bayer HealthCare

From: Kumar, Rita [mailto:Kumar.Rita@epa.gov]
Sent: Tuesday, November 03, 2015 3:51 PM
To: Doug Spilker
Subject: A question about 11556-116 and -117
Importance: High

Doug: I need to know if CRP certification was submitted for these two imidacloprid pet products. I did not find a certification in the jacket. A quick response will be greatly appreciated. Thanks.

Regards,
Rita

The information contained in this e-mail is for the exclusive use of the intended recipient(s) and may be confidential, proprietary, and/or legally privileged. Inadvertent disclosure of this message does not constitute a waiver of any privilege. If you receive this message in error, please do not directly or indirectly use, print, copy, forward, or disclose any part of this message. Please also delete this e-mail and all copies and notify the sender. Thank you.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

July 24, 2015

MEMORANDUM

Subject: Name of Pesticide Product: SERGEANT'S 9.1% IMIDACLOPRID
SQUEEZE-ON FOR DOGS
EPA Reg. No. /File Symbol: 2517-RTU
DP Barcode: DP 427019
Decision No.: 498903
Action Code: R315
E-Sub#: --
PC Code: 129099 (Imidacloprid: 9.1%)

From: Byron T. Backus, Ph.D., Toxicologist
CITAB
Registration Division (7505P)

Byron T. Backus
July - 24 - 2015

Through: John Redden, M.S., Senior Risk Assessor
CITAB
Registration Division (7505P)

JCR

To: Rita Kumar/Venus Eagle RM 01
IVB3
Registration Division (7505P)

Registrant: SERGEANT'S PET CARE PRODUCTS, INC.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129099 Imidacloprid	9.10%
<u>Other Ingredient(s):</u>	<u>90.90%</u>
TOTAL	100.00%

ACTION REQUESTED: The Risk Manager requests:

"...Please provide a...full review of this me-too application for a dog squeeze-on product. This is an e-submission, and all the information is in Documentum – cover letter, CSFs, data matrix, label. All companion animal data are cited. Copies of the cover letter and proposed label are enclosed here..."

BACKGROUND: In the cover letter dated December 19, 2014 the registrant has stated that this new end-use product is substantially similar to EPA Reg. Nos. 11556-117, -119, -120 and -122.

From the proposed label for EPA Reg. No. 2517-RTU, doses are 0.4 mL (0.014 fl. oz.) for dogs weighing 3½ to 10 lbs, 1.0 mL (0.034 fl. oz.) for dogs weighing 11-20 lbs, 2.5 mL (0.085 fl. oz.) for dogs weighing 21-55 lbs, and 4.0 mL (0.135 fl. oz.) for dogs weighing more than 55 lbs.

According to the data matrix (dated December 19, 2014) for EPA File Symbol 2517-RTU the registrant has cited the following studies to satisfy the companion animal safety data requirements for this product: MRIDs 43679607, 43679608, 44099801, and 44179801.

PREVIOUS REVIEWS:

1. The study in MRID 43679607 was reviewed in HED (TXR 0011821, sign-off date 03/05/96) with the following summary:

Nine adult dogs of mixed breed (3 males, 6 females, one male and two females/group) were dermally exposed to Imidacloprid, 10% Spot-On. Dose levels were 50 mg/kg/day x 1 day, and 50 mg/kg/day x 3 days. Controls received placebo (formulation less active ingredient) at 50 mg/kg/day x 3 days.

No major treatment related dermal, clinical signs, body weight effects or clinical chemistry changes were observed. Necropsy was not done due to lack of toxicosis. The study demonstrates that adult dogs can tolerate up to 50 mg/kg without significant reactions.

This...study is classified as Acceptable when combined with another study, and satisfies the requirement for a domestic animal study in the dog, 18 lb (8 kg) body weight and above. The number of animals/group is too small and not in keeping with general study practice. However, when data are combined with the companion study in the dog (MRID 43679608), the information is considered useful.

2. The study in MRID 43679608 was reviewed in HED (TXR 0011821, sign-off date 03/05/96) with the following summary:

18 adult dogs of various breeds (3 males and 3 females/group) were dermally exposed to Imidacloprid, 10% Spot-On formulation at seven-day intervals for a total of eight treatments. Dose levels were 10 or 50 mg/kg. Controls received placebo (formulation less active ingredient) at 50 mg/kg.

No major treatment related dermal, clinical signs, body weight effects or clinical chemistry/hematology were observed. Necropsy was not done due to lack of toxicosis. The study demonstrates that adult dogs can tolerate up to 50 mg/kg of the active ingredient without significant reactions. Inadequate testing was done in dogs less than four months old.

This repeated dose dermal study is classified as Acceptable and satisfies the requirements for a General Safety Evaluation for Topical Use (96-1) in the dog.

3. The study in MRID 44099801 was reviewed in HED (TXR 0012322, sign-off date 09/24/97) with the following summary:

In a domestic animal safety study (MRID #44099801), six 7 week-old puppies/sex were treated with AdvantageTM (9.1% imidacloprid) at 5X the recommended use rate (2.0 mL if < 10 lbs; 5.0 mL if > 10 lbs) at weekly intervals for eight treatments. Six puppies/sex were treated with the vehicle control at the recommended use rate (0.4 mL if < 10 lbs; 1.0 mL if > 10 lbs) at weekly intervals for eight treatments. There was no evidence of treatment-related toxicity in clinical signs or clinical pathology parameters. All animals gained weight during the study. It was demonstrated that 7 week-old puppies can tolerate a dose of 5X the recommended use rate.

The study is considered acceptable and satisfies the draft guideline requirements (81-6) for a domestic animal safety study.

4. There is no record of a review for the study in MRID 44179801 [Shmidl, J.; Arther, R. (1996) Acute Oral Toxicity Evaluation of Imidacloprid (Advantage) in Dogs: Lab Project Number: TR-96D-010: 74764: J:USERS\LINDA\NOREPORT\JAS0171.RPT. Unpublished study prepared by Bayer Corp., Animal Health. 10 p.]. The following is a summary of that study:

The study was conducted to evaluate the acute toxicity of the formulation and the formulation minus the active ingredient (placebo) when administered orally at the topical use rate. The labeled use rate is 1.0 mL for dogs weighing 11 to 20 lb; 2.5 mL for 21 to 55 lb and 5.0 mL for dogs weighing > 55 lb. Group 1 dogs received a single treatment of placebo (formulation minus the active ingredient) equivalent to use rate volume. Group 2 dogs received a single treatment of the formulation at the use rate volume.

The treatment volumes were placed in gelatin capsules and administered directly in the throat area. The gelatin capsules were swallowed intact.

Two dogs in Group 2 vomited at approximately one hour following treatment. None of the remaining 10 dogs had any clinical signs.

The purpose and protocol of this study are inconsistent with the 870.7200 Guidelines. This study, while providing relevant information, does not satisfy the 870.7200 data requirements.

5. The study in MRID 44099801 does not support a minimum weight of 3½ lbs. From Table 2 (p. 9 of MRID 44099801) the initial weights of the 6 male puppies ranged from 1.8 to 3.0 kg, and the initial weights of the 6 female puppies ranged from 1.5 to 2.1 kg. The mean weight of the 4 lowest weight male puppies (1.8, 1.8, 2.3 and 2.5 kg) and the four lowest weight female puppies (1.5, 1.7, 1.8 and 1.8 kg) was 1.9 (± a standard deviation of 0.33) kg, equal to 4.19 (± 0.73) lbs. This study supports a minimum weight of 4 lbs (1.81 kg), not 3½ lbs (1.59 kg), and the label must be revised accordingly.

6. From p. 4 of MRID 44099801 the puppies had birthdates of March 16, 1996 through March 19, 1996. From p. 5 the first treatment was on May 3, 1996, so the puppies were from 45 to 48 days old on that date. This study supports a minimum age of 7 weeks, as proposed by the registrant.
7. With the revision of minimum weight from 3½ to 4 lbs, the companion animal safety (870.7200) data requirements for the registration of 2517-RTU have been satisfied.

Kumar, Rita

From: Mary Hunt <mhunt@exponent.com>
Sent: Thursday, May 14, 2015 4:22 PM
To: Kumar, Rita
Cc: Stephanie Sarraino
Subject: UPDATE EPA File Symbols 2517-RTG, -RTU, -RTL & -RTA

5978431

Hi, Rita,

This is informational only.

I just wanted to provide you with an update on revised documents for the Sergeant's four subject pending spot on products. Per our earlier discussion, these were documents that had been emailed to the Agency, but not uploaded into Documentum. There were 4 CDs delivered today to the front end with revised documents to upload into Documentum as follows:

Sergeant's 9.1% Imidacloprid Spot On for Cats (EPA File Symbol 2517-RTG), D498685

- Revised product label v15.1 dated 3/02/2015

Sergeant's 9.1% Imidacloprid Squeeze On for Dogs (EPA File Symbol 2517-RTU), D498903

- Revised product label v15.1 dated 3/02/2015

Sergeant's Imidacloprid + Pyriproxyfen Spot on for Cats (EPA File Symbol 2517-RTL), D498686

- Revised product label v15.1 dated 3/01/2015
- Basic and Alternate Source #1 CSFs (EPA Form 8570-4) dated 3/02/2015
- Formulator's Exemption (EPA Form 8570-27) dated 3/02/2015

Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs (EPA File Symbol 2517-RTA), D498900

- Revised product label v15.1 dated 3/02/2015
- Basic and Alternate Source #1 CSFs (EPA Form 8570-4) dated 3/02/2015
- Formulator's Exemption (EPA Form 8570-27) dated 3/02/2015

All should be in order now, but if you should have any questions, please do not hesitate to contact me.

Thank you for all your help,
Mary

Mary McKinney Hunt

Managing Regulatory Consultant

E*ponent[®], Inc

1150 Connecticut Avenue, Suite 1100 | Washington, DC 20036 |

p: 202.549.9761 | e-mail: mhunt@exponent.com | web: www.exponent.com



Sergeant's Pet Care Products, Inc.

10077 South 134th Street • Omaha, NE 68138- 3710 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

April 20, 2015

Venus Eagle, PM 1
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Dear Ms. Eagle:

Sergeant's Pet Care Products, Inc. (EPA Company Number 2517), authorizes Exponent, Inc. (1150 Connecticut Avenue, NW, Suite 1100, Washington DC, 20036) to act on our behalf, as an Authorized Representative, for all necessary interactions regarding our product registration applications and registrations. Please note that this does not change the current filed Authorized Agent for Sergeant's Pet Care Products, Inc.

The Exponent, Inc. contacts include as follows:

Jim Messina and/or Mary M. Hunt and/or Reg Coler
Exponent, Inc.
1150 Connecticut Ave., NW
Suite 1100
Washington, DC 20036
(202) 772-4932 / (202) 549-9761 / (202) 772-4965
(202) 772-4979 fax
jmessina@exponent.com / mhunt@exponent.com / rcoler@exponent.com

If you have any questions, please contact me at (402) 938-7079 or khoskins@sergeants.com.

Sincerely,

Kelly R. Hoskins
Manager of Regulatory Affairs

cc: Jim Messina, Exponent, Inc.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

SIMILARITY CLINIC MEMORANDUM:

Subject: EPA Reg. No.: 2517-RTU/9.1% Imidacloprid Squeeze On for Dogs
DP Barcode: 425127
PC Code: 129099

From: Marianne Lewis, Biologist
Insecticides/Rodenticides Branch
Registration Division (7505P)

To: Venus Eagle, PM 01
Invertebrate/Vertebrate Branch 3
Registration Division (7505P)

Applicant: Sergeant's Pet Care Products, Inc
10077 South 134th Street
Omaha, NE 68138-3710

Marianne Lewis
JCR 1/20/15

FORMULATION FROM EPA Reg. No. 2517-RTU LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Imidacloprid:	9.1%
<u>Inert Ingredient(s):</u>	90.9%
Total	100.0%

BACKGROUND: The registrant is claiming substantial-similarity to EPA Reg. No. 11556-117 and is citing specific MRID's to support the registration of their new product, EPA Reg. No. 2517-RTU. The MRID's are as follows: 436796-01 (81-1), 436796-02 (81-2), 436796-03 (81-3), 436796-04 (81-4) 436796-05 (81-5) and 436796-06 (81-6).

After comparing the CSF from the subject product and the CSF from the test material used in the studies, the EPA will be allow the registrant to cite the studies listed above for the subject product. The following acute toxicity categories will be assigned to the subject product: acute oral (81-1) – III; acute dermal (81-2) – III; acute inhalation (81-3) – IV; primary eye irritation (81-4) – II; primary skin irritation (81-5) – IV; and will be classified as a non sensitizer (81-6).

RECOMMENDATIONS:

- The subject product will be assigned the Toxicity Categories listed above.
- The subject product will be classified as a non sensitizer.

The acute toxicity profile for EPA Reg. No. 2517-RTU is currently:

Acute Oral	III
Acute Dermal	III
Acute Inhalation	IV
Primary Eye	II
Primary Dermal	IV
Skin sensitization	non sensitizer

NOTE: The acute toxicity requirements have been satisfied for the subject product.

LABELING:

ID #: 002517-RTU SERGEANTS 9.1% IMIDACLOPRID SQUEEZE
ON FOR DOGS

RESTRICTED USE LABELING:

Based on primary eye irritation Toxicity Category II – residential use

SIGNAL WORD: **WARNING** **AVISO**

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Causes substantial but temporary eye injury. Harmful if swallowed. Harmful if absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin. Wear protective eyewear (goggles, safety glasses, face shield), long sleeved shirt, long pants, shoes, socks and chemical resistant gloves (barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, or viton, selection category C).

FIRST AID:

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Note to CRM/PM/Registrant:

The proposed label should contain a Note to Physician which addresses the primary eye irritation Toxicity Category II. The following statements are some suggested types of information that could be included, if applicable, in the Note to Physicians:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

Maggie 347-0257
Lindsey-347-0506



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEE

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

~~CONTAINS CONFIDENTIAL BUSINESS INFORMATION~~

DP BARCODE No.: D427018
PC CODE: 129099
FOOD USE: No

FILE SYMBOL NO.: 2517-RTU
ACTION CODE: R 315
PRODUCT NAME: Sergeant's 9.1% Imidacloprid Squeeze On for Dogs

DECISION No.: 498903

DATE OUT: August 27, 2015

SUBJECT: End-Use Product Chemistry Review
Product Name: Sergeant's 9.1% Imidacloprid Squeeze On for Dogs

FROM: Bruce F. Kitchens, Chemist
Product Chemistry Team
Chemistry, Inerts and Toxicology Assessment Branch/RD (7505P)

Bruce F. Kitchens
27 Aug 2015
SDM 8/27/15

TO: RM 01, Venus Eagle/Rita Kumar
Invertebrate and Vertebrate Branch 3/RD (7505P)

INTRODUCTION:

The registrant, Sergeant's Pet Care Products, Incorporated, is submitting an application to register the proposed end-use product, Sergeant's 9.1% Imidacloprid Squeeze On for Dogs. The active ingredient in this product is Imidacloprid (98.0% pai) at a label nominal concentration of 9.1% a.i. This product is intended for use as an insecticide for dogs. In addition, the registrant states that the proposed product is substantially similar in composition to EPA Reg. No. 11556-117 Advantage 10. In support of this request, the registrant is submitting a proposed basic and three alternate CSFs (Confidential Statements of Formula) all dated 19 Dec 2014; a draft label and product chemistry data contained in MRID#s 494692-01 through 494692-06. The Chemistry, Inerts and Toxicology Assessment Branch (CITAB) has been asked to review this submission.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient: Imidacloprid (9.10% ai)

Formulation Type: RTU

2. Has the registrant claimed substantial similarity to a registered product?

[X] Yes; [] No; [] NA; if yes give the registration number of the cited product.

EPA Reg. No. 11556-117

DP BARCODE No.: D427018

FILE SYMBOL NO.: 2517-RTU

DECISION No.: 498903

PC CODE: 129099

ACTION CODE: R 315

FOOD USE: No

PRODUCT NAME: Sergeant's 9.1% Imidacloprid Squeeze On for Dogs

3. All of the source materials of the active ingredient are derived from registered sources- ☒ Yes ☐ No

4. All inert ingredients have been screened by IIAB and are approved for the proposed labeled uses.

5. Confidential Statement of Formula:

☒ Basic - Dated: 19 Dec 2014

Resubmitted Dated:

☒ Alternate (1,2,3) – Dated: 19 Dec 2014

Resubmitted Dated:

Alternate CSF complies with 40 CFR 152.43

☒ Yes ☐ No ☐ NA

6. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF concurs with product label (PR Notice 91-2).

☒ Yes, if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)

☒ Yes; ☐ No; if not, explain below

Metallic equivalent: ☐ Yes ☒ NA

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid Equivalent: ☐ Yes ☒ NA

b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes; ☐ No; ☒ NA

Methanol at > 4%: ☐ Yes; ☐ No; ☒ NA

Sodium nitrate/sodium nitrite ☐ Yes; ☐ No; ☒ NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No; if yes explain below:

7. Group A: Product Chemistry Data

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	494692-01
830.1600	Description of materials used to produce the product		X		A	494692-01
830.1650	Description of formulation process		X		A	494692-01
830.1670	Discussion on the formation of impurities		X		A	494692-01
830.1700	Preliminary analysis			X	NA	
830.1750	Certified limits (158.350)	Standard certified limits	X			see basic csf 12/19/14
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	494692-02

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

DP BARCODE No.: D427018
PC CODE: 129099
FOOD USE: No

FILE SYMBOL NO.: 2517-RTU
ACTION CODE: R 315
PRODUCT NAME: Sergeant's 9.1% Imidacloprid Squeeze On for Dogs

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Yellow liquid with an odor characteristic of organic solvents	A	494692-03 494692-04
830.6314	Oxidation/Reduction	Not expected to be oxidized or reduced based on chemical structures of the components	A	494692-03
830.6315	Flammability	98.5°C	A	494692-03 494692-06
830.6316	Explodability	Product does not contain explosive components.	NA	
830.6317	Storage stability	Active ingredient content remained stable when stored in glass bottles at 54°C for 14-days. Active ingredient content increased slightly when stored in PE tubes at 54°C for 14-days.	A	494692-05
830.6320	Corrosion Characteristics	No signs of damage or corrosion observed after 14-days storage at 54°C.	A	494692-05
830.7000	pH	Product is not dispersible with water.	NA	
830.7100	Viscosity	6.60 MPas at 20°C	A	494692-03, 494692-04
830.7300	Density (units)	1.099 g/cm ³ at 20°C	A	494692-03 494692-04

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress; U = Upgradeable.

DP BARCODE No.: D427018

PC CODE: 129099

FOOD USE: No

FILE SYMBOL NO.: 2517-RTU

ACTION CODE: R 315

DECISION No.: 498903

PRODUCT NAME: Sergeant's 9.1% Imidacloprid Squeeze On for Dogs

CONCLUSIONS:

CITAB has reviewed the product chemistry data submitted for the proposed end-use product and has concluded that:

1. The basic formula CSF for the proposed end-use product, Sergeant's 9.1% Imidacloprid Squeeze On for Dogs dated 19 Dec 2014 is acceptable.

The proposed alternate formula CSFs (alt. 1-3) for the proposed end-use product, Sergeant's 9.1% Imidacloprid Squeeze On for Dogs all dated 19 Dec 2104 are acceptable.

2. This submission satisfies the data requirements as specified in 40 CFR 158.320, 158.325, 158.335, 158.340, 158.350, and 158.355 with respect to product identity and composition, description of materials used to produce the product, description of formulation process, discussion of formation of impurities, certified limits, and enforcement analytical method.
3. This submission satisfies the data requirements as specified in 40 CFR 158.310 with respect to physical and chemical properties.
4. The proposed product has been determined to be substantially similar in composition to EPA Reg. No. 11556-117 Advantage 10.

Kumar, Rita

From: Marchese, Jacquelyn
Sent: Thursday, May 28, 2015 10:25 AM
To: Kumar, Rita
Subject: 2517-RTG, 2517-RTU Pass Technical Screen

Hi Rita,

2517-RTG and 2517-RTU pass the efficacy technical screen. Let me know if you have any questions.

Thanks,
Jackie

Jacquelyn Marchese
Entomologist
OCSPP/OPP/RD/IVB3
Email: Marchese.Jacquelyn@epa.gov
Phone: (703) 347-0559



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

May 11, 2015

MEMORANDUM:

Subject: Name of Pesticide Product: SERGEANT'S 9.1% IMIDACLOPRID QUEEZE-ON FOR DOGS
EPA Reg. No. /File Symbol: 2517-RTU
DP Barcode: DP 427019 (screening review)
Decision No.: 498903
Action Code: R315
PC Codes: 129099 (Imidacloprid: 9.1%)

From: Byron T. Backus, Ph.D., Toxicologist *Byron T. Backus*
IVB1
Registration Division (7505P) *May 11, 2015*
Eugenia McAndrew

To: Rita Kumar RM 01
IVB3
Registration Division (7505P)

Registrant: SERGEANT'S PET CARE PRODUCTS, INC.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129099 Imidacloprid	9.1%
<u>Other Ingredients:</u>	<u>90.9%</u>
TOTAL	100.0%

ACTION REQUESTED: "Please provide a technical screen and full review of this me-too application for a dog squeeze-on product..."

COMMENTS AND RECOMMENDATIONS:

1. The registrant is citing MRIDs 43679607, 43679608, 44099801 and 44179801 to satisfy the companion animal (adult dogs and puppies) safety study data requirements for the registration of 2517-RTU.
2. After a search in OPPIN query, it is concluded that these citations are sufficient to allow a full review to determine whether the companion animal safety data requirements for the registration of 2517-RTU have been satisfied and if the proposed dosages, minimum age and minimum weight are supported.



Sergeant's Pet Care Products, Inc.

10077 South 134th Street • Omaha, NE 68138- 3710 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

April 20, 2015

Venus Eagle, PM 1
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Dear Ms. Eagle:

Sergeant's Pet Care Products, Inc. (EPA Company Number 2517), authorizes Exponent, Inc. (1150 Connecticut Avenue, NW, Suite 1100, Washington DC, 20036) to act on our behalf, as an Authorized Representative, for all necessary interactions regarding our product registration applications and registrations. Please note that this does not change the current filed Authorized Agent for Sergeant's Pet Care Products, Inc.

The Exponent, Inc. contacts include as follows:

Jim Messina and/or Mary M. Hunt and/or Reg Coler
Exponent, Inc.
1150 Connecticut Ave., NW
Suite 1100
Washington, DC 20036
(202) 772-4932 / (202) 549-9761 / (202) 772-4965
(202) 772-4979 fax
jmessina@exponent.com / mhunt@exponent.com / rcoler@exponent.com

If you have any questions, please contact me at (402) 938-7079 or khoskins@sergeants.com.

Sincerely,

Kelly R. Hoskins
Manager of Regulatory Affairs

cc: Jim Messina, Exponent, Inc.

Kumar, Rita

From: Mary Hunt <mhunt@exponent.com>
Sent: Tuesday, April 28, 2015 3:38 PM
To: Kumar, Rita
Subject: RE: Sergeant's pet product applications
Attachments: Transmittal for Dog Imid + PPF Submission.pdf

Hi, Rita,

I've figured it out! Please see below, and do not hesitate to call me if you have any questions or need further clarification.

For Imidacloprid-only containing products 2517-RTU (dog) and 2517-RTG (cat):

New Sergeant's Product Chemistry data was submitted under 2517-RTU (transmittal doc emailed earlier today), and that same new data is cited for 2517-RTG to support its product chemistry. The companion animal safety studies are listed for each product under Toxicology Requirements, Guideline 870.7200, in the respective data matrices. No CRP data is required as the acute toxicity did not trigger CRP testing/packaging.

For the imidacloprid/pyriproxyfen containing products, 2517-RTA (dog) and 2517-RTL (cat):

Again, new Sergeant's Product Chemistry was submitted under 2517-RTA (transmittal attached), and the same product chemistry data was cited to support the cat application, 2517-RTL. Also, a new acute inhalation toxicity waiver request and a new acute oral toxicity study have been submitted under 2517-RTA, and the same toxicity data was cited to support the cat application, 2517-RTL. Note that the companion animal safety studies are listed for each product under Toxicology Requirements, Guideline 870.7200, in the respective data matrices. Again, the requirement for CRP testing/packaging was not triggered by the acute toxicity data.

I hope this is helpful. Again, please just give me a call if you have further questions.

Thank you,
Mary

Mary McKinney Hunt

Managing Regulatory Consultant

Exponent[®], Inc

1150 Connecticut Avenue, Suite 1100 | Washington, DC 20036 |

p: 202.549.9761 | e-mail: mhunt@exponent.com | web: www.exponent.com

From: Kumar, Rita [<mailto:Kumar.Rita@epa.gov>]

Sent: Tuesday, April 28, 2015 12:16 PM

To: Mary Hunt

Subject: RE: Sergeant's pet product applications

Thanks, Mary. So, this product chemistry data is to support all four registrations? Also, am I correct in assuming that all other data were cited? In the data matrix, I find only acute toxicity and efficacy data citations, but nothing for companion animal or CRP. Can you please clarify. Thanks.

Rita

From: Mary Hunt [<mailto:mhunt@exponent.com>]

Sent: Tuesday, April 28, 2015 11:58 AM

To: Kumar, Rita
Cc: Kelly Hoskins; Eagle, Venus; Stephanie Sarraino
Subject: RE: Sergeant's pet product applications

Hi, Rita,

Thank you for the email. I don't know if it is helpful to you, but these were submitted electronically, and my understanding was that a transmittal was submitted. That being said, please see the attached transmittal and note that all data was submitted under the 2517-RTU imidacloprid dog spot on. Please let me know if you need any other information or further clarification.

Thanks, again,
Mary

From: Kumar, Rita [<mailto:Kumar.Rita@epa.gov>]
Sent: Tuesday, April 28, 2015 11:46 AM
To: Mary Hunt
Cc: Kelly Hoskins; Eagle, Venus
Subject: Sergeant's pet product applications
Importance: High

Hi Mary: I am doing a preliminary review of these applications. I noticed that there is no transmittal document. Can you please clarify what new data you are submitting to support these four cat and dog products, esp. what is being done for product chemistry. A transmittal document is helpful for us to know what new data are submitted, and we can assume that rest of the data in data matrix are cited.

Regards,
Rita

Kumar, Rita

From: Mary Hunt <mhunt@exponent.com>
Sent: Tuesday, April 21, 2015 9:57 AM
To: Kumar, Rita
Cc: Eagle, Venus
Subject: RE: New registration applications for imidacloprid
Attachments: Sergeants Exponent Agent Letter April 2015.pdf

Hi, Rita,

Please see the attached, updated Sergeant's letter, authorizing Exponent as representative. Please let me know if you have any questions.

Thank you,
Mary

Mary McKinney Hunt
Managing Regulatory Consultant
E^xponent[®], Inc
1150 Connecticut Avenue, Suite 1100 | Washington, DC 20036 |
p: 202.549.9761 | e-mail: mhunt@exponent.com | web: www.exponent.com

From: Kumar, Rita [<mailto:Kumar.Rita@epa.gov>]
Sent: Monday, April 20, 2015 12:39 PM
To: Mary Hunt
Cc: Eagle, Venus
Subject: RE: New registration applications for imidacloprid

I think that would be prudent. But then make sure these LOAs are updated when someone who is authorized leaves the company.
Rita

From: Mary Hunt [<mailto:mhunt@exponent.com>]
Sent: Monday, April 20, 2015 11:43 AM
To: Kumar, Rita
Cc: Eagle, Venus
Subject: RE: New registration applications for imidacloprid

Hi, Rita,

Please let me reach out to the client, and see if we can get that letter updated for the Agency. Rita, there are a number of people who work with Jim Messina on Sergeant's projects. Should the letter list all?

Thank you,
Mary

From: Kumar, Rita [<mailto:Kumar.Rita@epa.gov>]
Sent: Monday, April 20, 2015 7:40 AM
To: Mary Hunt

Cc: Eagle, Venus

Subject: RE: New registration applications for imidacloprid

Hi Mary: This letter of authorization (LOA) specifically mentions Jim and Rick. It would be better if we have an updated LOA which also mentions your name, since we mostly communicate with you re registration matters. How soon can you get me an updated LOA?

Regards,

Rita

From: Mary Hunt [<mailto:mhunt@exponent.com>]

Sent: Friday, April 03, 2015 5:18 PM

To: Kumar, Rita

Cc: Eagle, Venus

Subject: FW: New registration applications for imidacloprid

Hi, Rita,

Please see the attached Sergeant's letter, authorizing Exponent as representative.

Please let me know if you have any questions, regarding the file jackets: 2517-RTG, 2517-RTU, 2517-RTA, and 2517-RTL (please email chain below).

Thank you,

Mary

Mary McKinney Hunt

Managing Regulatory Consultant

Exponent[®], Inc

1150 Connecticut Avenue, Suite 1100 | Washington, DC 20036 |

p: 202.549.9761 | e-mail: mhunt@exponent.com | web: www.exponent.com

From: Kelly Hoskins [<mailto:Kelly.Hoskins@perrigo.com>]

Sent: Thursday, April 02, 2015 5:15 PM

To: Kumar, Rita; Mary Hunt

Cc: Eagle, Venus; James Messina

Subject: RE: New registration applications for imidacloprid

Rita,

Yes Exponent is an Agent of Sergeant's and has been on file for years, we will get you the necessary documents.

Kelly Hoskins | Regulatory Affairs

Sergeant's Pet Care Products, Inc.

A Perrigo Company

10077 South 134th Street

Omaha, NE 68138-3710

T: 402.938.7079

F: 402.938.7179

E: khoskins@sergeants.com | sergeants.com



From: Kumar, Rita [<mailto:Kumar.Rita@epa.gov>]
Sent: Thursday, April 02, 2015 3:50 PM
To: Kelly Hoskins
Cc: Eagle, Venus
Subject: New registration applications for imidacloprid

Hi Kelly: I have just started the preliminary review of the following four pet spot-on or squeeze-on applications from Sergeants:

2517-RTG
2517-RTU
2517-RTA
2517-RTL

In the jackets for these, I have seen correspondence with Mary Hunt of Exponent, but did not find an authorization letter from Sergeants assigning Exponent (Mary Hunt) as the designated agent. Can you please send me a letter of authorization to this effect, and also advise if I should just communicate with mary, or you, or both regarding these applications? Thanks.

Best Regards,
Rita

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 29, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

SERGEANT'S PET CARE PRODUCTS, INC.
PO.BOX : 540399
OMAHA, NE 68154-0399

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 19-DEC-14. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

CONTACT PERSON (Return to)

James Messina
Exponent, Inc.
1150 Connecticut Ave. NW, Suite 1100
Washington, DC 20036

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is prepared to support an EPA registration application for the new "me-too" end-use product, Sergeant's 9.1% Imidacloprid Squeeze On for Dogs.

SUBMITTAL DATE:

December 19, 2014

Volume	Study Title	MRID No.
1	Administrative Materials	49469200
2	Group A Product Chemistry for Sergeant's 9.1% Imidacloprid Spot-on Products	49469201
3	Analytical Method for Sergeant's 9.1% Imidacloprid Spot-On Products	49469202
4	Summary of Group B Product Chemistry and Waivers for Sergeant's 9.1% Imidacloprid Spot-on Products	49469203
5	Physical and Chemical Characteristics: Color, Viscosity, and Density for Sergeant's 9.1% Imidacloprid Spot-on Products	49469204
6	Accelerated 14-Day Storage Stability and Corrosion Characteristics of Sergeant's 9.1% Imidacloprid Spot-on Products	49469205
7	Flashpoint for Sergeant's 9.1% Imidacloprid and 9.1% Imidacloprid + 0.46% Pyriproxyfen Spot-on Products	49469206

esubmission

2517-RTU

Memorandum

Date: 01 / 09 / 2015

To: PM 01, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

CONTACT PERSON (Return to)

James Messina
Exponent, Inc.
1150 Connecticut Ave. NW, Suite 1100
Washington, DC 20036

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This submission is prepared to support an EPA registration application for the new "me-too" end-use product, Sergeant's 9.1% Imidacloprid Squeeze On for Dogs.

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6	Accelerated 14-Day Storage Stability and Corrosion Characteristics of Sergeant's 9.1% Imidacloprid Spot-on Products	49469205
7	Flashpoint for Sergeant's 9.1% Imidacloprid and 9.1% Imidacloprid + 0.46% Pyriproxyfen Spot-on Products	49469206



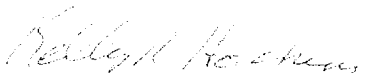
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date: December 19, 2014		EPA Reg No./File Symbol: 2517-NEW		Page 1 of 3	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® 9.1% Imidacloprid Squeeze On for Dogs			
Ingredient: Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry					
830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1750	Group A Product Chemistry for Sergeant's 9.1% Imidacloprid Spot-on Products	49469201	Sergeant's Pet Care Products	OWN	
830.1800	Analytical Method for Sergeant's 9.1% Imidacloprid Spot-On Products	49469202	Sergeant's Pet Care Products	OWN	
830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6319, 830.6321, 830.7000, 830.7100, 830.7300, 830.7520	Summary of Group B Product Chemistry and Waivers for Sergeant's 9.1% Imidacloprid Spot-on Products	49469203	Sergeant's Pet Care Products	OWN	
830.6302, 830.7100, 830.7300	Physical and Chemical Characteristics: Color, Viscosity, and Density for Sergeant's 9.1% Imidacloprid Spot-on Products	49469204	Sergeant's Pet Care Products	OWN	
830.6317, 830.6320	Accelerated 14-Day Storage Stability and Corrosion Characteristics of Sergeant's 9.1% Imidacloprid Spot-on Products	49469205	Sergeant's Pet Care Products	OWN	
830.6315	Flashpoint for Sergeant's 9.1% Imidacloprid and 9.1% Imidacloprid + 0.46% Pyriproxyfen Spot-on Products	49469206	Sergeant's Pet Care Products	OWN	
Toxicology Data Requirements					
870.1100	Acute Oral Toxicity Study with Imidacloprid (Bay T-7391) 10% Pour On in Rats: Lab Project Number: 74585: 95-012-DO. Unpublished study prepared by Bayer Corp. 26 p.	43679601	Bayer HealthCare LLC	OLD	
870.1200	Acute Dermal Toxicity Study with Imidacloprid (Bay T-7391) 10% Pour On in Rats: Lab Project Number: 74584: 95-022-DQ. Unpublished study prepared by Bayer Corp. 24 p.	43679602	Bayer HealthCare LLC	OLD	
870.1300	Acute Four-Hour Inhalation Toxicity Study with Imidacloprid (Bay T-7391) 10% Pour On in Rats: Lab Project Number: 74589: 94-042-CT. Unpublished study prepared by Bayer Corp. 31	43679603	Bayer HealthCare LLC	OLD	
870.2400	Primary Eye Irritation Study with Imidacloprid (Bay T-7391) 10% Pour On in Rabbits: Lab Project Number: 74588: 94-335-CO. Unpublished study prepared by Bayer Corp. 19 p.	43679604	Bayer HealthCare LLC	OLD	
Signature 		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date December 19, 2014	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB Nos. 2070-0060; 2070-0057;
2070-0107; 2070-0122; 2070-0164

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DATA MATRIX

Date: December 19, 2014 **EPA Reg No./File Symbol:** 2517-NEW **Page** 2 of 3

Applicant's/Registrant's Name & Address
Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710

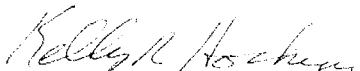
Product:
Sergeant's® 9.1% Imidacloprid Squeeze On for Dogs

Ingredient: Imidacloprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2500	Primary Dermal Irritation Study with Imidacloprid (Bay T-7391) 10% Pour On in Rabbits: Lab Project Number: 74586: 94-325-CN. Unpublished study prepared by Bayer Corp. 19 p.	43679605	Bayer HealthCare LLC	OLD	
870.2600	Dermal Sensitization Study with Imidacloprid (Bay T-7391) 10% Pour On in Guinea Pigs: Lab Project Number: 74587: 94-324-CW. Unpublished study prepared by Bayer Corp. 24 p.	43679606	Bayer HealthCare LLC	OLD	
870.7200	Acute Toxicity Evaluation for Dermal Treatment of Dogs with Imidacloprid (Bay t 7391) Spot-on: Lab Project Number: 74580: TR-94D-010. Unpublished study prepared by Miles Inc. 19 p.	43679607	Bayer HealthCare LLC	OLD	
870.7200	General Safety Evaluation for Topical Use of Imidacloprid (Bay t 7391) Spot-On On Dogs: Lab Project Number: 74590: TR-95D-005. Unpublished study prepared by Bayer Corp. 40 p.	43679608	Bayer HealthCare LLC	OLD	
870.7200	General Safety Evaluation for Topical Use of Imidacloprid (Advantage) Spot-On on Puppies: Lab Project Number: TR-96D-003: 74730: 10332. Unpublished study prepared by Bayer Corp. 47 p.	44099801	Bayer HealthCare LLC	OLD	
870.7200	Acute Oral Toxicity Evaluation of Imidacloprid (Advantage) in Dogs: Lab Project Number: TR-96D-010: 74764: J:USERS\LINDA\NOREPORT\JAS0171.RPT. Unpublished study prepared by Bayer Corp., Animal Health. 10 p.	44179801	Bayer HealthCare LLC	OLD	

Product Performance Test Guidelines

810.3300	Efficacy Evaluation of Bay t 7391 (Imidacloprid) 10% Solution Applied Dermally for Control of Fleas on Dogs: Lab Project Number: 74572. Unpublished study prepared by AgResearch Consultants, Inc. 35 p.	43679609	Bayer HealthCare LLC	OLD	
810.3300	Efficacy Confirmation of NTN 33893 (Imidacloprid) Solution Applied Dermally for Control of Fleas on Dogs: Lab Project Number: 74541: MID 194. Unpublished study prepared by AgResearch Consultants, Inc. 15 p.	43679610	Bayer HealthCare LLC	OLD	

Signature


Name and Title
Kelly R. Hoskins, Director of Regulatory Affairs

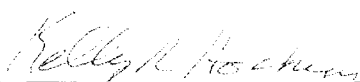
Date
December 19, 2014



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: December 19, 2014		EPA Reg No./File Symbol: 2517-NEW		Page 3 of 3	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® 9.1% Imidacloprid Squeeze On for Dogs			
Ingredient: Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Comparative Evaluation of How Quickly Advantage and Frontline (Fipronil) Top Spot Kill Fleas on Dogs: (final Report): Lab Project Number: 74800: PLRS 9665: 150.341. Unpublished study prepared by Professional Laboratory & Research Services, Inc. 51 p.	44256901	Bayer HealthCare LLC	OLD	
810.3300	Imidacloprid Topical Formulation: Larvicidal Effect Against Ctenocephalides felis in the Surroundings of Treated Dogs: (Revised Report): Lab Project Number: 74828: 97REPORT/ARTHER/HOPKINS.DOC. Unpublished study prepared by Bahrs Hill Research Station. 14 p.	44256902	Bayer HealthCare LLC	OLD	
810.3300	Evaluation of the Effects of Shampooing or Water Immersion on the Initial and Residual Efficacy of Advantage for Flea Control on Dogs: Lab Project Number: BD#296: 150.353: BD 296. Unpublished study prepared by AgResearch Consultants, Inc. 27 p.	44256903	Bayer HealthCare LLC	OLD	
Signature 		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date December 19, 2014	

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

CONTACT PERSON (Return to)

James Messina
Exponent, Inc.
1150 Connecticut Ave. NW, Suite 1100
Washington, DC 20036

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is prepared to support an EPA registration application for the new "me-too" end-use product, Sergeant's 9.1% Imidacloprid Squeeze On for Dogs.

SUBMITTAL DATE:

December 19, 2014

Volume	Study Title	MRID No.
1	Administrative Materials	49469200
2	Group A Product Chemistry for Sergeant's 9.1% Imidacloprid Spot-on Products	49469201
3	Analytical Method for Sergeant's 9.1% Imidacloprid Spot-On Products	49469202
4	Summary of Group B Product Chemistry and Waivers for Sergeant's 9.1% Imidacloprid Spot-on Products	49469203
5	Physical and Chemical Characteristics: Color, Viscosity, and Density for Sergeant's 9.1% Imidacloprid Spot-on Products	49469204
6	Accelerated 14-Day Storage Stability and Corrosion Characteristics of Sergeant's 9.1% Imidacloprid Spot-on Products	49469205
7	Flashpoint for Sergeant's 9.1% Imidacloprid and 9.1% Imidacloprid + 0.46% Pyriproxyfen Spot-on Products	49469206

Kumar, Rita

From: Mary Hunt <mhunt@exponent.com>
Sent: Tuesday, April 28, 2015 11:58 AM
To: Kumar, Rita
Cc: Kelly Hoskins; Eagle, Venus; Stephanie Sarraio
Subject: RE: Sergeant's pet product applications
Attachments: Transmittal for Dog Submission.pdf

Hi, Rita,

Thank you for the email. I don't know if it is helpful to you, but these were submitted electronically, and my understanding was that a transmittal was submitted. That being said, please see the attached transmittal and note that all data was submitted under the 2517-RTU imidacloprid dog spot on. Please let me know if you need any other information or further clarification.

Thanks, again,
Mary

From: Kumar, Rita [mailto:Kumar.Rita@epa.gov]
Sent: Tuesday, April 28, 2015 11:46 AM
To: Mary Hunt
Cc: Kelly Hoskins; Eagle, Venus
Subject: Sergeant's pet product applications
Importance: High

Hi Mary: I am doing a preliminary review of these applications. I noticed that there is no transmittal document. Can you please clarify what new data you are submitting to support these four cat and dog products, esp. what is being done for product chemistry. A transmittal document is helpful for us to know what new data are submitted, and we can assume that rest of the data in data matrix are cited.

Regards,
Rita



Sergeant's Pet Care Products, Inc.

10077 South 134th Street • Omaha, NE 68138- 3710 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

April 20, 2015

Venus Eagle, PM 1
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Dear Ms. Eagle:

Sergeant's Pet Care Products, Inc. (EPA Company Number 2517), authorizes Exponent, Inc. (1150 Connecticut Avenue, NW, Suite 1100, Washington DC, 20036) to act on our behalf, as an Authorized Representative, for all necessary interactions regarding our product registration applications and registrations. Please note that this does not change the current filed Authorized Agent for Sergeant's Pet Care Products, Inc.

The Exponent, Inc. contacts include as follows:

Jim Messina and/or Mary M. Hunt and/or Reg Coler
Exponent, Inc.
1150 Connecticut Ave., NW
Suite 1100
Washington, DC 20036
(202) 772-4932 / (202) 549-9761 / (202) 772-4965
(202) 772-4979 fax
jmessina@exponent.com / mhunt@exponent.com / rcoler@exponent.com

If you have any questions, please contact me at (402) 938-7079 or khoskins@sergeants.com.

Sincerely,

Kelly R. Hoskins
Manager of Regulatory Affairs

cc: Jim Messina, Exponent, Inc.

Hill, Shaunta

From: Mary Hunt <mhunt@exponent.com>
Sent: Tuesday, March 03, 2015 3:19 PM
To: Hill, Shaunta
Subject: pending EPA Reg. 2517-RTG & 2517-RTU
Attachments: 2517-RTG Revised Label 3-2-15.pdf; 2517-RTU Revised Label_3-2-15.pdf

Hi, Shaunta,

Per our discussions regarding the two pending applications for new pesticide products, please see the attached revised documents for Sergeant's 9.1% Imidacloprid Spot On for Cats (2517-RTG), and Sergeant's 9.1% Imidacloprid Squeeze On for Dogs (2517-RTU). I understand that you will forward these documents to the PM, Venus Eagle.

You may recall, these actions were required by the Agency to be changed from a PRIA3 category R301 to category R315.

Note that the Master label has been revised to reduce [brackets] in efficacy claims to make the statements clearer. After a review of the data matrices for these products, it appears no revised EPA form 8570-34 Certification with Respect to Citation of Data is required.

Please do not hesitate to call me if you have any questions or need further clarification.

Thank you,
Mary

Mary McKinney Hunt

Managing Regulatory Consultant

Exponent[®], Inc

1150 Connecticut Avenue, Suite 1100 | Washington, DC 20036 |

p: 202.549.9761 | e-mail: mhunt@exponent.com | web: www.exponent.com

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Recd. 3/24/15

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02 March 2014

Version 15.1

EPA Reg. No. 2517-RTU

Information in [] is optional.

Information in { } is note to reviewer.

Page 1 of 11

FRONT PANEL

Dogs Squeeze On Imidacloprid

[Optional text appears in brackets/parenthesis – the final label may include some or all of the optional text on front, back or side label panels]

Sergeant's® 9.1% Imidacloprid Squeeze On for Dogs

{One of the following statements will appear on appropriate weight band market label on front panel as required per Agency's pet spot-on mitigation measures:}

For use ONLY on dogs [[&][and] puppies] [weighing] 3½ [-][to] 10 lbs. and over 7 weeks [old][of age]

For use ONLY on dogs [[&][and] puppies] [weighing] 3½ [-][to] 10 lbs. and 7 weeks [of age] or older

For use ONLY on dogs [[&][and] puppies] [weighing] 11 [-][to] 20 lbs. and over 7 weeks [old][of age]

For use ONLY on dogs [[&][and] puppies] [weighing] 11 [-][to] 20 lbs. and 7 weeks [of age] or older

For use ONLY on dogs [[&][and] puppies] [weighing] 21 [-][to] 55 lbs. and over 7 weeks [old][of age]

For use ONLY on dogs [[&][and] puppies] [weighing] 21 [-][to] 55 lbs. and 7 weeks [of age] or older

For use ONLY on dogs [[&][and] puppies] [weighing] [more than][over][>] 55 lbs. and over 7 weeks [old][of age]

For use ONLY on dogs [[&][and] puppies] [weighing] [more than][over][>] 55 lbs. and 7 weeks [of age] or older

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] 3½ [-][to] 10 lbs.

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] 3½ [-][to] 10 lbs.

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] 11 [-][to] 20 lbs.

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] 11 [-][to] 20 lbs.

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] 21 [-][to] 55 lbs.

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] 21 [-][to] 55 lbs.

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] [more than][over][>] 55 lbs.

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] [more than][over][>] 55 lbs.

[1.5cm x 1.5cm on final or as indicated]



ACTIVE INGREDIENT:

Imidacloprid.....9.10%

OTHER INGREDIENTS:90.90%

[TOTAL]100.00%

Sergeant's[®] Master Label

02 March 2014

Version 15.1

EPA Reg. No. 2517-RTU

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Page 2 of 11

KEEP OUT OF REACH OF CHILDREN WARNING

[See [Back][or][Side][Label[s]][Panel[s]] for Additional Precautionary Statements]

NET CONTENT: X fl oz [Y – X fl oz applicators]

[0.014 fl oz (0.4 mL) [tubes][vials][applicators][pipettes]]

[0.034 fl oz (1.0 mL) [tubes][vials][applicators][pipettes]]

[0.085 fl oz (2.5 mL) [tubes][vials][applicators][pipettes]]

[0.135 fl oz (4.0 mL) [tubes][vials][applicators][pipettes]]

[ABNs]

[SENTRY[®] Vet for Dogs Imidacloprid]

[SENTRY[®] Vet Advanced Flea for Dogs]

[SENTRY[®] Vet FleaGuard for Dogs]

[SENTRY[®] Vet Vantage for Dogs]

[SENTRY[®] Vet Flea Vantage for Dogs]

[SENTRY[®] Advanced for Dogs Imidacloprid]

[SENTRY[®] Advanced FleaGuard for Dogs]

[SENTRY[®] Advanced Vantage for Dogs]

[SENTRY[®] Advanced Flea Vantage for Dogs]

[SENTRY[®] Advanced VetSpot for Dogs]

[PetArmor[®] Vantage for Dogs]

[PetArmor[®] Advant for Dogs]

[PetArmor[®] FleaGuard for Dogs]

[PetArmor[®] Advanced for Dogs]

[PetArmor[®] Flea Vantage for Dogs]

[PetArmor[®] Adv Flea for Dogs]

[PetArmor[®] Adv.Flea for Dogs]

[PetArmor[®] AdVet for Dogs]

[Active Ingredient Reference Statements]

[Contains imidacloprid, [the] [same] active ingredient used in

{OR}

[Compare to the active ingredient in

{OR}

[Contains [the] [same] active ingredient used in

{OR}

[[Brand Name] [This product] contains imidacloprid, [the] [same] active ingredient used in

{OR}

[[Brand Name] [This product] contains imidacloprid, compared to [the] [same] active ingredient used in

[Advantage[®] 10 Topical Solution] [Advantage[®] for Small Dogs] [Advantage[®] TM 10

(Imidacloprid) Topical Solution]

[Advantage[®] 20 Topical Solution] [Advantage[®] for Medium Dogs] [Advantage[®] TM 20

(Imidacloprid) Topical Solution]

[Advantage[®] 55 Topical Solution] [Advantage[®] for Large Dogs] [Advantage[®] 55 (Imidacloprid) Topical Solution]

Sergeant's[®] Master Label

02 March 2014

Version 15.1

EPA Reg. No. 2517-RTU

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Page 3 of 11

[*Advantage[®] 100 Topical Solution*] [*Advantage[®] for Extra Large Dogs*] [*Advantage[®] 100 (Imidacloprid) Topical Solution*].

*)

[*][Brand Name][This product] is not manufactured or distributed by Bayer Healthcare LLC, the makers of

[*Advantage[®] 10 Topical Solution*] [*Advantage[®] for Small Dogs*] [*Advantage[®] TM 10 (Imidacloprid) Topical Solution*]

[*Advantage[®] 20 Topical Solution*] [*Advantage[®] for Medium Dogs*] [*Advantage[®] TM 20 (Imidacloprid) Topical Solution*]

[*Advantage[®] 55 Topical Solution*] [*Advantage[®] for Large Dogs*] [*Advantage[®] 55 (Imidacloprid) Topical Solution*]

[*Advantage[®] 100 Topical Solution*] [*Advantage[®] for Extra Large Dogs*] [*Advantage[®] 100 (Imidacloprid) Topical Solution*].*)

[Compare to

[*Advantage[®] 10 Topical Solution*] [*Advantage[®] for Small Dogs*] [*Advantage[®] TM 10 (Imidacloprid) Topical Solution*],

[*Advantage[®] 20 Topical Solution*] [*Advantage[®] for Medium Dogs*] [*Advantage[®] TM 20 (Imidacloprid) Topical Solution*],

[*Advantage[®] 55 Topical Solution*] [*Advantage[®] for Large Dogs*] [*Advantage[®] 55 (Imidacloprid) Topical Solution*],

[*Advantage[®] 100 Topical Solution*] [*Advantage[®] for Extra Large Dogs*] [*Advantage[®] 100 (Imidacloprid) Topical Solution*],

contains the same active ingredient.*]

[**Advantage[®] 10 Topical Solution*] [*Advantage[®] for Small Dogs*] [*Advantage[®] TM 10 (Imidacloprid) Topical Solution*],

[*Advantage[®] 20 Topical Solution*] [*Advantage[®] for Medium Dogs*] [*Advantage[®] TM 20 (Imidacloprid) Topical Solution*],

[*Advantage[®] 55 Topical Solution*] [*Advantage[®] for Large Dogs*] [*Advantage[®] 55 (Imidacloprid) Topical Solution*],

[*Advantage[®] 100 Topical Solution*] [*Advantage[®] for Extra Large Dogs*] [*Advantage[®] 100 (Imidacloprid) Topical Solution*]

is a registered trademark of Bayer Healthcare LLC.]

[Fleas]

[Prevents [further] flea infestation for [[four][4] weeks][1 month] with [just] one treatment]

[Prevents [further] flea infestation for [[four][4] weeks][1 month] with [just] one application]

[Brand Name] Prevents flea infestation for [four][4] weeks][1 month]

[Kills fleas within 12 hours [of application] on dogs]

[Kills reinfesting fleas within 2 hours]

[Kills [adult] fleas before they lay eggs]

[[Brand Name][This product] kills fleas and may reduce the incidence of a hypersensitivity skin disorder called flea allergy dermatitis (FAD), which may be caused by the feeding activity of fleas.]

[Use [of Brand Name][of this product] kills fleas and may reduce incidence of flea bite hypersensitivity] [and][or] [flea allergy dermatitis] [FAD]]

[Use [of Brand Name][of this product] kills fleas and may reduce incidence of [flea bite

Sergeant's[®] Master Label

02 March 2014

Version 15.1

EPA Reg. No. 2517-RTU

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Page 4 of 11

hypersensitivity] [and][or] flea allergy dermatitis [FAD]]
[Monthly treatment [with Brand Name][with this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]
[Monthly treatment [with Brand Name][with this product] kills fleas and may reduce incidence of flea bite hypersensitivity [and][or] [flea allergy dermatitis] [FAD]]
[Kills flea larvae in dog's environment following contact with treated dog]
[Apply monthly [for optimal flea control]]
[Apply monthly [to control and prevent fleas]]
[Kills fleas]
[Complete Flea Protection]
[Complete Flea Control]
[Optimal Flea Control]
[Optimal Flea Protection]
[Advanced Flea Control]
[Advanced Flea Protection]
[Kills fleas in 12 hours, continues to kill for 4 weeks]
[Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation]
[Kills fleas, which may be a source of flea allergy dermatitis in 12 hours]
[Flea protection]
[Active against fleas]
[Kills fleas on [puppies and] dogs]
[[Brand Name] Offers protection against fleas]
[Flea control for puppies and dogs [over 7 weeks [old]][of age]]
[Flea control for puppies and dogs [7 weeks [of age] or older]]
[Kills fleas within 12 hours [and prevents flea infestations for [a][one] [month] [four weeks]]]

[All Others]

[Apply to [dogs and] puppies over 7 weeks old]
[Apply to [dogs and] puppies 7 weeks or older]
[SENTRY[®]]
[PetArmor[®]]
[[Sergeant's] Caring For Your Pets Since 1868]
[For Dogs]
[For use ONLY on dogs]
[Specially Formulated for Dogs and Puppies [Over 7 Weeks [Old]][of Age]]
[Specially Formulated for Dogs and Puppies [7 Weeks [of Age] or Older]]
[Dogs and Puppies [over 7 weeks [old]][of age]]
[Dogs and Puppies [7 weeks [of age] or older]]
[Can be used on puppies [over 7 weeks [old]][of age]][7 weeks [of age] or older]]
[The Only Flea Protection You Need For Your Dog[s]!]
[Original Vet Strength]
[Fast Acting] [Long Lasting]
[Convenient]
[Easy application]
[Easy to apply product]
[Easy to Use [Application]]
[One Step Hassle Free Protection!]
[Waterproof]
[Remains effective even after shampooing, swimming, or exposure to sunlight [and][or] [rain]]

Sergeant's® Master Label

02 March 2014

Version 15.1

EPA Reg. No. 2517-RTU

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Page 5 of 11

[Remains effective, even after bathing, water immersion, or exposure to [sunlight] [and][or] rain]
[Once a month treatment]

[Apply once every [4 weeks] [month] [30 days]!]

[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]

[For year-round protection, apply [Brand Name][this product] monthly]

[Best if used year round!]

[X Applications] [4 Week Supply] [1 Month Supply]

[One Application] [8 Week Supply] [2 Month Supply]

[Two Applications] [12 Week Supply] [3 Month Supply]

[Three Applications] [16 Week Supply] [4 Month Supply]

[Four Applications] [20 Week Supply] [5 Month Supply]

[Five Applications] [24 Week Supply] [6 Month Supply]

[Six Applications] [48 Week Supply] [12 Month Supply]

[9 Applications] [52 Week Supply] [24 Month Supply]

[12 Applications] [104 Week Supply]

[24 Applications]

[[for] Small Dog[s] [[3.5][3½] [to][–] 10 lbs.]]

[[for] Medium Dog[s] [11 [to][–] 20 lbs.]]

[[for] Large Dog[s] [21[to][–] 55 lbs.]]

[[for] Extra Large Dog[s] [Over 55 lbs.]]

[Direct to skin [tube][vial][applicator][pipette]]

[Easy to Use] [tube][vial][applicator][pipette]

[Clean cut [open] [tube][vial][applicator][pipette]]

[No-mess [open] [tube][vial][applicator][pipette]]

[Clip-tip design [tube][vial][applicator][pipette][!]]

{END – FRONT PANEL}

BACK PANEL/SIDE PANEL OR INSERT

**Dogs Squeeze On
Imidacloprid**

[The active ingredient in [Brand name][this product] is [imidacloprid,] formulated for fast acting
[and long lasting] control of fleas on dogs.] [[Brand Name][This product] kills fleas within 12
hours and prevents further flea infestations for [up to] [[4][four] weeks][[1][one] month][30
days].]

READ ENTIRE LABEL BEFORE EACH USE.

USE ONLY ON DOGS AND PUPPIES 7 WEEKS OF AGE OR OLDER.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. WARNING. Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Harmful if swallowed. Avoid contact with skin. Wash hands thoroughly with soap and warm water after handling.

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities, while rare, may occur after using ANY pesticide product for dogs. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing dogs.

Sergeant's® Master Label

02 March 2014

Version 15.1

EPA Reg. No. 2517-RTU

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Page 6 of 11

FIRST AID	
If In Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If Swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on Skin or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on animals other than dogs. Do not allow your dog to ingest this product. Do not use on puppies under 7 weeks of age or less than [[3.5][3½]] [11] [21] [55] lbs. Use entire contents of [tube][vial][applicator][pipette] on each dog. [Do not split one [tube][vial][applicator][pipette] between dogs.] Do not use multiple [tube][vial][applicator][pipette]s on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.

Side Effects: Monitor your dog after application. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your dog and continue to monitor your dog for the next 24 hours.

[1.5 cm x 1.5 cm on final or as indicated]



DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. Contact your veterinarian if applied to a cat or ingested by a cat.

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02 March 2014

Version 15.1

EPA Reg. No. 2517-RTU

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Page 7 of 11

{OUTER PACKAGING}

How to Open: Remove product [tube[s]][vial[s]][applicator[s]][pipette[s]] from the package. [Separate one [tube][vial][applicator][pipette] from the others.] Hold the [tube][vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply: Invert [tube][vial][applicator][pipette] over dog and use open end to part dog's hair. Squeeze [tube][vial][applicator][pipette] firmly to apply all of the solution to the dog's skin, as directed below. Do not apply more often than once every [30 days][4 weeks][month].

{For cartons containing 0.4 mL (0.014 fl oz) applicator tubes}

Only For Dogs Weighing [3.5][3½] [-][to] 10 lbs. [Do not apply to dogs weighing less than [3.5][3½] lbs. [including small dogs and puppies, only 7 weeks or older]] Apply one [tube][vial][applicator][pipette] 0.4 mL (0.014 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail] [as a spot [on][to] the dog's back between the shoulder blades][as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades.][This allows for a more direct application to the skin.]

{For cartons containing 1.0 mL (0.034 fl oz) applicator tube}

Only For Dogs Weighing 11 [-][to] 20 lbs. [Do not apply to dogs weighing less than 11 lbs.] Apply one [tube][vial][applicator][pipette] 1.0 mL (0.034 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail] [as a spot [on][to] the dog's back between the shoulder blades][as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades.][This allows for a more direct application to the skin.]

{For cartons containing 2.5 mL (0.085 fl oz) applicator tube}

Only For Dogs Weighing 21 [-][to] 55 lbs. [Do not apply to dogs weighing less than 21 lbs.] Apply one [tube][vial][applicator][pipette] 2.5 mL (0.085 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail] [as a spot [on][to] the dog's back between the shoulder blades][as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades.][This allows for a more direct application to the skin.]

{For cartons containing 4.0 mL (0.135 fl oz) applicator tube}

Only For Dogs Weighing 55 lbs. or greater. [Do not apply to dogs weighing less than 55 lbs.] [Do not use two [tube][vial][applicator][pipette]s on dogs greater than 55 lbs.] Apply one [tube][vial][applicator][pipette] 4.0 mL (0.135 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail] [as a spot [on][to] the dog's back between the shoulder blades][as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades.][This allows for a more direct application to the skin.]

FREQUENCY OF APPLICATION

[Use [Brand Name {or} this product] monthly for control of flea[s] [infestations].]
[[Studies show that] [Brand Name][This product] kills fleas within 12 hours of application and [lasts {or} protects] [for [up to] [[four][4] weeks][30 days][one month].]

Sergeant's® Master Label

02 March 2014

Version 15.1

EPA Reg. No. 2517-RTU

Information in [] is optional.

Information in { } is note to reviewer.

Page 8 of 11

[[Brand Name {or} This product] kills reinfesting fleas within [2][two] hours and prevents further infestations of fleas [for [up to] [[four][4] weeks][30 days][one month]].]

[If your dog is at high risk for flea reinfestation [, or in a highly infested environment], apply monthly.]

[Apply monthly for optimal flea control.]

[[Brand Name {or} This product] is waterproof and remains effective, even after bathing, swimming, or exposure to sunlight [and][or] [rain].]

[Allow treated area to dry thoroughly.]

[Do not reapply for [[four][4] weeks][30 days].]

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove [tube][vial][applicator][pipette] from the pack until ready to use. Store only in original container in a cool [(below 77°F)[/][25°C)], dry area inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: If empty: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's][SENTRY][PetArmor®]Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

[Satisfaction Guaranteed][If you are not satisfied, we will make it right with a replacement or refund.]

In Case of Emergency, call: 1-800-781-4738

Non-Emergency, call: 1-800-224-PETS (7387)

[Coupon(s) inside or on outside of box]

[Made in USA]

[Distributed by:] [Manufactured by:]

Sergeant's Pet Care Products, Inc.

Omaha, NE 68138-3710

{END - BACK/SIDE PANEL}

EPA Reg. No. 2517-RTU

EPA Est. No. XXXXX-XX-XX

[BAR CODE AREA]

{START - OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE OR INSERT}

[How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.]

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02 March 2014

Version 15.1

EPA Reg. No. 2517-RTU

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Page 9 of 11

[Clip. Part. Squeeze.]

Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting proven flea protection where it needs to be.]

[Application Instructions][Directions for Use]

How to Open:

1. Remove product [tube[s]][vial[s]][applicator[s]][pipette[s]] from the package.
2. [Separate one [tube][vial][applicator][pipette] from the others.] Hold the [tube][vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Invert [tube][vial][applicator][pipette] over dog and use open end to part dog's hair.
2. Squeeze [tube][vial][applicator][pipette] firmly to apply all of the solution [on] [to] the dog's skin [as a spot to the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

[Look at the Label (Look at the Label icon) [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist]

- [1] Read the label completely and follow directions
- [2] Weigh your dog
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after [treatment] [application] to avoid chance of ingestion
- [6] Do NOT split [tube][vial][applicator][pipette] between dogs][and use the ENTIRE [tube][vial][applicator][pipette] contents]

[Brand Name][This product]

[Monthly reminder card]

[1][2][3][4][5][6][12][24][Month [Treatment] [Application] Tracker][Carecard]

[For year-round protection, apply [Brand Name][this product] monthly.]

[Dog's Name (Empty blank for owner to fill in name)]

[Dog's Weight (Empty blank for owner to fill in name)]

[First][1st][Second][2nd][Third][3rd][Fourth][4th][Fifth][5th][Sixth][6th][Seventh][7th][Eighth][8th][Ninth][9th][Tenth][10th][Eleventh][11th][Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)

[Application Date][Date of Application]

[Calendar stickers with Brand Name]

[Place stickers on your calendar as a reminder to reapply [Brand Name][this product] [in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Place sticker on your calendar [or refrigerator] to remind yourself to apply [Brand Name][this product] to your dog]

[33% More Free]

[Bonus Size]

[Buy 3 get 1 free]

Sergeant's® Master Label

02 March 2014

Version 15.1

EPA Reg. No. 2517-RTU







Information in [] is optional.

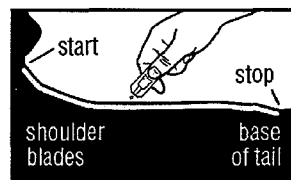
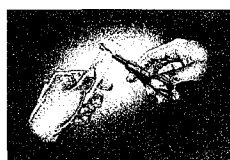
Information in { } is note to reviewer.

Page 10 of 11

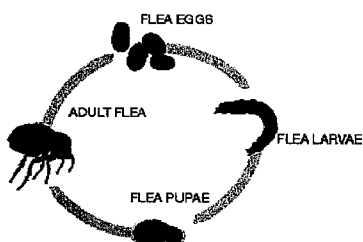
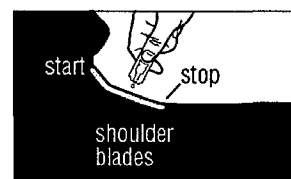
[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [Brand Name][this product]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

[Each optional graphic below may or may not appear anywhere on the finished label]

	Adult Flea	
	Fleas	
	Flea Larvae	



DO NOT USE
ON CATS



MADE IN THE
USA



MADE IN THE
USA
WITH GLOBAL MATERIALS

[Flea life cycle diagram] [Flea Life Cycle]

{END – OPTIONAL INSERT OR PACKAGE COPY}

Sergeant's[®] Master Label

02 March 2014

Version 15.1

EPA Reg. No. 2517-RTU

Information in [] is optional.

Information in { } is note to reviewer.


Page 11 of 11

TUBE/VIAL LABEL

**Dogs Squeeze On
Imidacloprid**

{Front Label}

{Back Label}

<p>[Brand Name (for dogs)] [X-Y] lbs. ≥7 wks Imidacloprid 9.10% 0.014 fl oz (or) 0.034 fl oz (or) 0.085 fl oz (or) 0.135 fl oz {label code}</p>	<p></p> <p>KEEP OUT OF REACH OF CHILDREN WARNING: Read directions and precautions before using. Use scissors to open. EPA REG. No. 2517-RTU {label code}</p>
----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

{EPA REG No may be on either the front or back label}

{END – TUBE/VIAL LABEL}

TRANSFER THIS JACKET TO:

RITA KUMAR

Jacket # 2517 - RTU

This jacket was transferred from: V EAGLE

FOR OFFICE

DATE: _____

TIME: _____

COMPLETE _____

Decision Seq: 498903

Action Code: R315, NEW END-USE NON-FOOD ANIMAL PRODUCT WITH SUB ...

Decision Status

FFS Start Date: 10-Mar-2015

Tentative Ind: No

Start/Stop Clock

FQPA Clock:

Tracking

Due Date: 10-Dec-2015

75-Day Due Date:

Days Elapsed:

Create Resubmission

OPP Target Due Date:

21-Day Due Date: 10-Mar-2015

FFS Original Decision:

FFS Letters

Negotiated Due Date:

90-Day Due Date: 08-Jun-2015

Waiver Documentation

Registrant



Predecisional

Due Date: 25-Nov-2015

Add to Bundle? ☐

Action Code History

Response Due Date:

Due Date:

Secondary Decision

Current Status: PENDING (09-Jan-2015)

Bundle ID:

Decision Bundle

75 Day Letters | 45/90 Day Screen | Primary Decisions | Decision Milestone

FFS Negotiated Due Dates | OPP Target Due Date | Decision Comments | Payment | Unmatched Payments

Decision Ownership | Receipts | Data Package | Reduced Risk | Meetings & Milestones | FFS Information

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S: 962069	Kumar, Rita	2517-RTU	10-Dec-2015	PENDING

me-too of 11556-117 ...send to pc, companion animal (30 day screen), & crp (as per acute tox) and perhaps efficacy -
tox review is completed

Viewing Record 1 of 1

Hill, Shaunta

From: Mary Hunt <mhunt@exponent.com>
Sent: Friday, February 13, 2015 3:39 PM
To: Hill, Shaunta
Subject: FW: Pay.gov Payment Confirmation: PRIA Service Fees

Hi, Shaunta,

FYI....

Thank you,
Mary

-----Original Message-----

From: notification@pay.gov [mailto:notification@pay.gov]
Sent: Friday, February 13, 2015 2:03 PM
To: Prince Bamaze
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25JPP3K6
Agency Tracking ID: 74752774031

Account Holder Name: Sergeants Pet Care Products Inc
Transaction Type: ACH Debit
Transaction Amount: \$19,892.00
Payment Date: 02/17/2015
Account Type: Business Checking
Routing Number: 121100782
Account Number: *****0100

Transaction Date: 02/13/2015 03:02:50 PM EST
Total Payments Scheduled: 1
Frequency: OneTime

Registration Number: 2517-RTG; -RTU;-RTL;-RTA
Company Name: SERGEANT'S
Company Number: 2517
Action Code: R315

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

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if this e-mail message contains a forwarded message or is a reply to a prior message, some or all of the contents of this message or any attachments may not have been produced by the sender. This notice is automatically appended to each e-mail message leaving the senders e-mail domain. Thank you.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 13, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
Or Pay On-Line at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-498685, D-498903, D-498686 & D-498900
EPA File Symbol or Registration Numbers: 2517-RTG, 2517-RTU, 2517-RTL & 2517-RTA
Prod. Names: SERGEANT'S 9.1% IMIDACLOPRID SPOT ON FOR CATS
SERGEANT'S 9.1% IMIDACLOPRID SQUEEZE ON FOR DOGS
SERGEANT'S IMIDACLOPRID + PYRIPROXYFEN SPOT ON FOR CATS
SERGEANT'S IMIDACLOPRID + PYRIPROXYFEN SQUEEZE ON FOR DOGS
EPA Receipt Date: 19-Dec-2014
EPA Company Number: 2517
Company Name: SERGEANT'S PET CARE PRODUCTS, INC.

MS. KELLY R. HOSKINS
SERGEANT'S PET CARE PRODUCTS, INC.
PO Box 540399
OMAHA, NE 68154-0399

SUBJECT: Recoding of Four Registration Applications Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has recoded your four applications for registration that are subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

These actions has been recoded as action code R315:

NEW END-USE NON-FOOD ANIMAL PRODUCT WITH SUBMISSION OF TWO OR MORE TARGET ANIMAL SAFETY STUDIES;INCLUDES DATA AND/OR WAIVERS OF DATA FOR ONLY:;PRODUCT CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);ANIMAL SAFETY STUDIES;CHILD RESISTANT PACKAGING;

The fee for action code R315 is \$8,400. We have received payment in the amount of \$1,806 each for symbol numbers 2517-RTG and 2517-RTU and \$5,048 each for symbol numbers 2517-RTL and 2517-RTA, so please remit payment in the amount of \$19,892 for all four applications within 14 days to:

By USPS:

USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 979074
St. Louis, MO 63197-9000

By Courier:

U.S. Bank
Government Lockbox 979074
1005 Convention Plaza
SL-MO-C2-GL
St. Louis, MO 63197
Telephone: (314) 425-1818

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

A PRIA decision time review period will not start until the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action within the next 14 days, the Agency will presume that you no longer want to pursue this action. The Agency will then reject your application and issue an invoice for any applicable outstanding fees.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 347-8961.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

21-Day Screen Completed by
Contractor

21-Day Expires on 1-9-15

Jacket # 2517-RTU
MRID# 494692

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

STEPHEN SCHAIK

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 12/14/14

Experts In-Processing Signature: MP Date 1/14/15 Fee Paid: Yes L

Division management contacted on issues No Yes Date

EPA Reg. Number: <u>2517-RTU</u>		EPA Receipt Date: <u>12/14/14</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes X	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes X	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

* Inerts approved for non-food use

* Submitted studies Passed PRN 11-3 Review

* Jacket Passed

22 1/13/15

MRID: 494692

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

R 300 and 301

100% identical (repack): YES or NO (circle one)

{If **yes**, it's a 100% repack - then product chemistry, acute toxicity and efficacy data are not required}

Data on Group A and B must be submitted - Group A and B can not be cited.

Guideline No.	Group A: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.1550	Product Identity & Composition	X	
830.1600	Description of materials used to produce the product	X	
830.1650	Description of formulation process	X	
830.1670	Discussion on the formation of impurities	X	
830.1700	Preliminary analysis	X	
830.1750	Certified limits (158.345)	X	
830.1800	Enforcement analytical method	X	

Guideline No.	Group B: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.6302	Color	X	
830.6303	Physical State	X	
830.6304	Odor	X	
830.6314	Oxidation/Reduction (Chemical incompatibility)	X	
830.6315	Flammability	X	
830.6316	Explodability	X	
830.6317	Storage stability	X	
830.6319	Miscibility	X	
830.6320	Corrosion Characteristics	X	
830.6321	Dielectric Breakdown voltage	X	
830.7000	pH	X	
830.7100	Viscosity	X	
830.7300	Density	X	

R 300 and 301

New products must provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cited	
		Yes	No
870.1100	Acute Oral (LD50)	X	
870.1200	Acute Dermal (LD50)	X	
870.1300	Acute Inhalation (LC50)	X	
870.2400	Acute Eye Irritation	X	
870.2500	Acute Dermal Irritation	X	
870.2600	Dermal Sensitization	X	

Efficacy – which guideline depends on the proposed label use and they must cite the data to be used for the bridging rationale.

Guideline No.	Efficacy Study Titles	Cited		Comments
		Yes	No	
810.3100	Soil Treatments for Imported Fire Ants			NOT req'd ↓
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments			
810.3300	Treatments to Control Pests of Humans and Pets	X		
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments			NOT req'd ↓
810.3500	Premises Treatments			
810.3600	Structural Treatments			
810.3800	Methods for Efficacy Testing of Termite Baits			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 9, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-498903
EPA File Symbol or Registration Number: 2517-RTU
Product Name: Sergeant's 9.1% Imidacloprid Squeeze On for Dogs
EPA Receipt Date: 19-Dec-2014
EPA Company Number: 2517
Company Name: SERGEANT'S PET CARE PRODUCTS, INC.

MS. KELLY R. HOSKINS
SERGEANT'S PET CARE PRODUCTS, INC.
PO Box 540399
OMAHA, NE 68154-0399

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R301

NEW PRODUCT; IDENTICAL OR SUBSTANTIALLY SIMILAR IN COMPOSITION AND USE TO A REGISTERED PRODUCT; REGISTERED SOURCE OF ACTIVE INGREDIENT; SELECTIVE DATA CITATION ONLY FOR DATA ON PRODUCT CHEMISTRY / ACUTE TOXICITY / PUBLIC HEALTH PEST EFFICACY, WHERE APPLICANT DOES NOT OWN ALL REQUIRED DATA NOR HAS AUTHORIZATION LETTER FROM DATA OWNER;

No additional payment is due at this time. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "m jk", is written over the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

70
{962069C~

This package includes the following

☒ New Registration

☐ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: _____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr.

1

Receipt No.

S-

962069

EPA File Symbol/Reg. No.

2517-RTU

Pin-Punch Date:

12/19/2014

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R301

Granted: R301

Amount Due: \$ 1,806.00

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: L. Roe

Date: 12/30/14

Remarks:

sim clinic

e-Submission

Receipt for Section 3

S: 962069

Milestone Email: khoskins@sergeants.com

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: New Registration

Fee For Service: ☒ Yes ☐ No

Billable: ☒ Yes ☐ No

Company: 2517 SERGEANT'S PET CARE PRODUCTS, INC.



Risk Manager: Registration Division, Risk Management Team 1

Product #: 2517-RTU Product Name: Sergeant's 9.1% Imidacloprid Squeeze On for

Override#:

Me Too

Section3

11556-117

Me Too Product

Name:

ADVANTAGE 10 TOPICAL SOLUTION

Application Date: 19-Dec-2014



OPP Rec'd Date: 19-Dec-2014



Front End Date: 22-Dec-2014



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Associated with e-Submission pkg 7016. Application for registration

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

CSF

View/Edit

e-Submission

-----Original Message-----

From: pay.gov.clev@clev.frb.org [mailto:pay.gov.clev@clev.frb.org]

Sent: Friday, January 09, 2015 11:05 AM

To: Prince Bamaze

Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or by email at yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 25J8AHFT

Agency Tracking ID: 74734456483

Account Holder Name: Sergeants Pet Care Products Inc

Transaction Type: ACH Debit

Transaction Amount: \$1,806.00

Payment Date: 01/12/2015

Account Type: Business Checking

Routing Number: 121100782

Account Number: *****0100

Transaction Date: 01/09/2015 12:04:47 PM EST

Total Payments Scheduled: 1

Frequency: OneTime

Registration Number: 2517-NEW

Company Name: SERGEANT'S

Company Number: 2517

Action Code: R301

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

NOTICE: This e-mail message and any attachments are confidential and intended solely for use of the intended recipient. If you are not the intended recipient, you should not review, retransmit, convert to hard copy, copy, use or disseminate this e-mail or any attachments to it. If you have received this e-mail in error, please immediately notify us by return e-mail and delete this message and any attachments from your computer system. Please note that if this e-mail message contains a forwarded message or is a reply to a prior message, some or all of the contents of this message or any attachments may not have been produced by the sender. This notice is automatically appended to each e-mail message leaving the senders e-mail domain. Thank you.

EPAUnited States
Environmental Protection Agency

Washington, DC 20460

☒ **Registration**
☐ **Amendment**
☐ **Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2517-NEW	2. EPA Product Manager Venus Eagle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sergeant's Pet Care Products, Inc./Sergeant's 9.1% Imidacloprid Squeeze On for Dogs	5. PM #1	
5. Name and Address of Applicant (Include ZIP Code) Sergeant's Pet Care Products, Inc. 10077 South 134 th Street Omaha, NE 68138-3710 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. 11556-117, -119, -120, -122 Nos. _____ Product Name <u>Advantage Topical Solution for Dogs</u>	

Section II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated XX-XX-XX
<input type="checkbox"/> Resubmission in response to Agency letter dated XX-XX-XX	<input checked="" type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Sergeant's Pet Care Products, Inc. is submitting a registration application for a new me-too end-use product, Sergeant's 9.1% Imidacloprid Squeeze On for Dogs. Sergeant's requests that the Agency review the me-too end-use product registration as a 4 month PRIA timeframe under R301.

Section III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. 0.014 fl oz (0.4 ml) 0.034 fl oz (1.0 ml) 0.085 fl oz (2.5 ml) 0.135 fl oz (4.0 ml)	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per Container 1, 2, 3, 4, 5, 6, 12, 24, 50, 75, 100 vials	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plastic Bag
*Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container Various (see above)	5. Location of Label Directions <input type="checkbox"/> On Can <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other Printed box <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name James B. Messina	Title Authorized Representative	Telephone No. (Include Area Code) (202) 772-4932	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature BY:	3. Title Director of Regulatory Affairs		
4. Typed Name: Kelly R. Hoskins	5. Date: December 19, 2014		

e-Submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710	EPA Registration Number/File Symbol 2517-NEW
Active Ingredient(s) and/or representative test compound(s) Imidacloprid	Date 12/19/2014
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor non-food	Product Name Sergeant's 9.1% Imidacloprid Squeeze On for Dogs

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Kelly R. Hoskins</i>	Date 12/19/2014	Typed or Printed Name and Title Kelly R. Hoskins, Director of Regulatory Affairs
--------------------------------------	--------------------	-------------------------------------------------------------------------------------



United States
Environmental Protection Agency
 Washington, DC 20460
Formulator's Exemption Statement
 (40 CFR 152.85)

Applicant's Name and Address Sergeant's Pet Care Products, Inc. 10077 South 134th Street Omaha, NE 68138-3710	EPA File Symbol/Registration Number 2517-NEW
	Product Name Sergeant's 9.1% Imidacloprid Squeeze On for Dogs
	Date of Confidential Statement of Formula (EPA Form 8570-4) 12/19/2014

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Imidacloprid

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

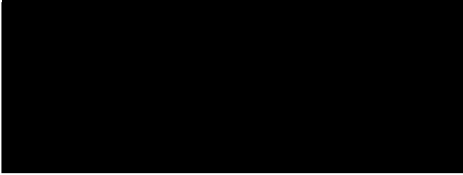

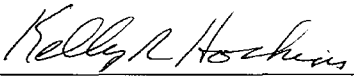
(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Imidacloprid Imidacloprid Imidacloprid Imidacloprid		
Signature 	Name and Title Kelly R. Hoskins, Director of Regulatory Affairs	Date 12/19/2014

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
 Copy 2 - Applicant copy

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Product Source Data May Be Subject to Confidential Treatment*



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: December 19, 2014	EPA Reg No./File Symbol: 2517-NEW	Page 1 of 3
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710	Product: Sergeant's® 9.1% Imidacloprid Squeeze On for Dogs	

Ingredient: Imidacloprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Sergeant's Pet Care Products	OWN	
			Sergeant's Pet Care Products	OWN	
			Sergeant's Pet Care Products	OWN	
			Sergeant's Pet Care Products	OWN	
			Sergeant's Pet Care Products	OWN	
			Sergeant's Pet Care Products	OWN	
			Sergeant's Pet Care Products	OWN	
			Bayer HealthCare LLC	OLD	
			Bayer HealthCare LLC	OLD	
			Bayer HealthCare LLC	OLD	
			Bayer HealthCare LLC	OLD	

Signature 	Name and Title Kelly R. Hoskins, Director of Regulatory Affairs	Date December 19, 2014
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX


Date: December 19, 2014 **EPA Reg No./File Symbol:** 2517-NEW **Page** 2 of 3

Applicant's/Registrant's Name & Address
Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710 **Product:**
Sergeant's® 9.1% Imidacloprid Squeeze On for Dogs

Ingredient: Imidacloprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
-------------------------------	----------------------	-------------	-----------	--------	------

			Bayer HealthCare LLC	OLD	
			Bayer HealthCare LLC	OLD	
			Bayer HealthCare LLC	OLD	
			Bayer HealthCare LLC	OLD	
			Bayer HealthCare LLC	OLD	
			Bayer HealthCare LLC	OLD	
			Bayer HealthCare LLC	OLD	
			Bayer HealthCare LLC	OLD	
			Bayer HealthCare LLC	OLD	

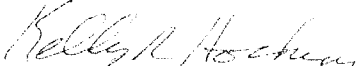
Signature 	Name and Title Kelly R. Hoskins, Director of Regulatory Affairs	Date December 19, 2014
---------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------	----------------------------------



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: December 19, 2014		EPA Reg No./File Symbol: 2517-NEW		Page 3 of 3	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® 9.1% Imidacloprid Squeeze On for Dogs			
Ingredient: Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer HealthCare LLC	OLD	
			Bayer HealthCare LLC	OLD	
			Bayer HealthCare LLC	OLD	
Signature 		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date December 19, 2014	

Sergeant's® Master Label

19 December 2014

Version 14.1

EPA Reg. No. 2517-NEW

Information in [] is optional.

Information in { } is note to reviewer.

Page 1 of 11

FRONT PANEL

Dogs Squeeze On Imidacloprid

[Optional text appears in brackets/parenthesis – the final label may include some or all of the optional text on front, back or side label panels]

Sergeant's® 9.1% Imidacloprid Squeeze On for Dogs

[ABNs]

[SENTRY Vet for Dogs Imidacloprid]

[SENTRY Vet Advanced Flea for Dogs]

[SENTRY Vet FleaGuard for Dogs]

[SENTRY Vet Vantage for Dogs]

[SENTRY Vet Flea Vantage for Dogs]

[SENTRY Advanced for Dogs Imidacloprid]

[SENTRY Advanced FleaGuard for Dogs]

[SENTRY Advanced Vantage for Dogs]

[SENTRY Advanced Flea Vantage for Dogs]

[SENTRY Advanced VetSpot for Dogs]

[PetArmor Vantage for Dogs]

[PetArmor Advant for Dogs]

[PetArmor FleaGuard for Dogs]

[PetArmor Advanced for Dogs]

[PetArmor Flea Vantage for Dogs]

[PetArmor Adv Flea for Dogs]

[PetArmor Adv.Flea for Dogs]

[PetArmor AdVet for Dogs]

For use ONLY on dogs [[&][and] puppies] [weighing] [[3.5][3½] [-][to] 10 lbs.] [11 [-][to] 20 lbs.] [21 [-][to] 55 lbs.] [[more than][over][>] 55 lbs.] and [over 7 weeks [old][of age]][7 weeks [of age] or older] {OR}
ONLY for dogs [[&][and] puppies]] [over 7 weeks [old][of age]][7 weeks [of age] or older] and [weighing] [[3.5][3½] [-][to] 10 lbs.] [11 [-][to] 20 lbs.] [21 [-][to] 55 lbs.] [[more than][over][>] 55 lbs.]

[1.5cm x 1.5cm on final or as indicated]



[Apply to [dogs and] [puppies] over 7 weeks old]

[Apply to [dogs and] [puppies] 7 weeks or older]

e-Submission

Sergeant's® Master Label

19 December 2014

Version 14.1

EPA Reg. No. 2517-NEW

Information in [] is optional.

Information in { } is note to reviewer.

Page 2 of 11

[Active Ingredient Reference Statements]

[Contains imidacloprid, [the] [same] active ingredient used in [Advantage® 10 Topical Solution] [Advantage® for Small Dogs] [Advantage® TM 10 (Imidacloprid) Topical Solution].*]
[Contains imidacloprid, [the] [same] active ingredient used in [Advantage® 20 Topical Solution] [Advantage® for Medium Dogs] [Advantage® TM 20 (Imidacloprid) Topical Solution].*]
[Contains imidacloprid, [the] [same] active ingredient used [Advantage® 55 Topical Solution] [Advantage® for Large Dogs] [Advantage® 55 (Imidacloprid) Topical Solution].*]
[Contains imidacloprid, [the] [same] active ingredient used in [Advantage® 100 Topical Solution] [Advantage® for Extra Large Dogs] [Advantage® 100 (Imidacloprid) Topical Solution].*]

[Compare to the active ingredient in [Advantage® 10 Topical Solution] [Advantage® for Small Dogs] [Advantage® TM 10 (Imidacloprid) Topical Solution].*]
[Compare to the active ingredient in [Advantage® 20 Topical Solution] [Advantage® for Medium Dogs] [Advantage® TM 20 (Imidacloprid) Topical Solution].*]
[Compare to the active ingredient in [Advantage® 55 Topical Solution] [Advantage® for Large Dogs] [Advantage® 55 (Imidacloprid) Topical Solution].*]
[Compare to the active ingredient in [Advantage® 100 Topical Solution] [Advantage® for Extra Large Dogs] [Advantage® 100 (Imidacloprid) Topical Solution].*]

[Contains [the] [same] active ingredient used in [Advantage® 10 Topical Solution] [Advantage® for Small Dogs] [Advantage® TM 10 (Imidacloprid) Topical Solution].*]
[Contains [the] [same] active ingredient used in [Advantage® 20 Topical Solution] [Advantage® for Medium Dogs] [Advantage® TM 20 (Imidacloprid) Topical Solution].*]
[Contains [the] [same] active ingredient used in [Advantage® 55 Topical Solution] [Advantage® for Large Dogs] [Advantage® 55 (Imidacloprid) Topical Solution].*]
Contains [the] [same] active ingredient used in [Advantage® 100 Topical Solution] [Advantage® for Extra Large Dogs] [Advantage® 100 (Imidacloprid) Topical Solution].*]

[Compare to [Advantage® 10 Topical Solution] [Advantage® for Small Dogs] [Advantage® TM 10 (Imidacloprid) Topical Solution], contains the same active ingredient.*]
[Compare to [Advantage® 20 Topical Solution] [Advantage® for Medium Dogs] [Advantage® TM 20 (Imidacloprid) Topical Solution], contains the same active ingredient.*]
[Compare to [Advantage® 55 Topical Solution] [Advantage® for Large Dogs] [Advantage® 55 (Imidacloprid) Topical Solution], contains the same active ingredient.*]
[Compare to [Advantage® 100 Topical Solution] [Advantage® for Extra Large Dogs] [Advantage® 100 (Imidacloprid) Topical Solution], contains the same active ingredient.*]

[[Brand Name] [products] [This product] contain(s) imidacloprid, [the] [same] [an] active ingredient used in [Advantage® 10 Topical Solution] [Advantage® for Small Dogs] [Advantage® TM 10 (Imidacloprid) Topical Solution].*]
[[Brand Name] [products] [This product] contain(s) imidacloprid, [the] [same] [an] active ingredient used in [Advantage® 20 Topical Solution] [Advantage® for Medium Dogs] [Advantage® TM 20 (Imidacloprid) Topical Solution].*]
[[Brand Name] [products] [This product] contain(s) imidacloprid, [the] [same] [an] active ingredient used in [Advantage® 55 Topical Solution] [Advantage® for Large Dogs] [Advantage® 55 (Imidacloprid) Topical Solution].*]

Sergeant's® Master Label

19 December 2014

Version 14.1

EPA Reg. No. 2517-NEW

Information in [] is optional.

Information in { } is note to reviewer.

Page 3 of 11

[[Brand Name] [products] [This product] contain(s) imidacloprid, [the] [same] [an] active ingredient used in [Advantage® 100 Topical Solution] [Advantage® for Extra Large Dogs] [Advantage® 100 (Imidacloprid) Topical Solution].*]

[[Brand Name] [products] [This product] contain(s) imidacloprid, compared to [the] [same] active ingredient used in [Advantage® 10 Topical Solution] [Advantage® for Small Dogs] [Advantage® TM 10 (Imidacloprid) Topical Solution].*]

[[Brand Name] [products] [This product] contain(s) imidacloprid, compared to [the] [same] active ingredient used in [Advantage® 20 Topical Solution] [Advantage® for Medium Dogs] [Advantage® TM 20 (Imidacloprid) Topical Solution].*]

[[Brand Name] [products] [This product] contain(s) imidacloprid, compared to [the] [same] active ingredient used in [Advantage® 55 Topical Solution] [Advantage® for Large Dogs] [Advantage® 55 (Imidacloprid) Topical Solution].*]

[[Brand Name] [products] [This product] contain(s) imidacloprid, compared to [the] [same] active ingredient used in [Advantage® 100 Topical Solution] [Advantage® for Extra Large Dogs] [Advantage® 100 (Imidacloprid) Topical Solution].*]

[[*][Brand Name][This product] is not manufactured or distributed by [Bayer Healthcare LLC] [Company name], the makers of [Advantage® 10 Topical Solution] [Advantage® for Small Dogs] [Advantage® TM 10 (Imidacloprid) Topical Solution].]

[[*][Brand Name][This product] is not manufactured or distributed by [Bayer Healthcare LLC] [Company name], the makers of [Advantage® 20 Topical Solution] [Advantage® for Medium Dogs] [Advantage® TM 20 (Imidacloprid) Topical Solution].]

[[*][Brand Name][This product] is not manufactured or distributed by [Bayer Healthcare LLC] [Company name], the makers of [Advantage® 55 Topical Solution] [Advantage® for Large Dogs] [Advantage® 55 (Imidacloprid) Topical Solution].]

[[*][Brand Name][This product] is not manufactured or distributed by [Bayer Healthcare LLC] [Company name], the makers of [Advantage® 100 Topical Solution] [Advantage® for Extra Large Dogs] [Advantage® 100 (Imidacloprid) Topical Solution].]

[*[Advantage® 10 Topical Solution] [Advantage® for Small Dogs] [Advantage® TM 10 (Imidacloprid) Topical Solution] is a registered trademark of Bayer Healthcare LLC.]

[*[Advantage® 20 Topical Solution] [Advantage® for Medium Dogs] [Advantage® TM 20 (Imidacloprid) Topical Solution] is a registered trademark of Bayer Healthcare LLC.]

[*[Advantage® 55 Topical Solution] [Advantage® for Large Dogs] [Advantage® 55 (Imidacloprid) Topical Solution] is a registered trademark of Bayer Healthcare LLC.]

[*[Advantage® 100 Topical Solution] [Advantage® for Extra Large Dogs] [Advantage® 100 (Imidacloprid) Topical Solution] is a registered trademark of Bayer Healthcare LLC.]

[Fleas]

[Prevents [further] flea infestation for [[four][4] weeks][1 month] with [just] one [treatment][application]

[Brand Name] Prevents flea infestation for [four][4] weeks][1 month]

[Kills fleas within 12 hours [of application] on dogs]

[Kills reinfesting fleas within 2 hours]

[Kills [adult] fleas before they lay eggs]

[[Brand Name][This product] kills fleas and may reduce the incidence of a hypersensitivity skin disorder called flea allergy dermatitis (FAD), which may be caused by the feeding activity of fleas.]

Sergeant's® Master Label

19 December 2014

Version 14.1

EPA Reg. No. 2517-NEW

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Page 4 of 11

[Use of [Brand Name][this product]] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] [flea allergy dermatitis] [FAD]]
[Monthly treatment with [Brand Name][this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] [flea allergy dermatitis] [FAD]]
[Kills flea larvae in dog's environment following contact with treated dog]
[Apply monthly [for optimal flea control][to control and prevent fleas]]
[Kills fleas]
[Complete Flea [Control] [Protection]]
[Optimal Flea [Control] [Protection]]
[Advanced Flea [Control] [Protection]]
[Kills fleas in 12 hours, continues to kill for 4 weeks]
[Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation]
[Kills fleas, which may be a source of flea allergy dermatitis [, within][in] 12 hours]
[Flea protection]
[Active against fleas]
[Kills fleas on [puppies] [and] [dogs]]
[[Brand Name] Offers protection against fleas]
[Flea control for puppies and dogs [over 7 weeks [old][of age]][7 weeks [of age] or older]]
[Kills fleas within 12 hours [and prevents flea infestations for [a][one] [month] [four weeks]]]

[All Others]

[[Sergeant's] Caring For Your Pets Since 1868]
[For Dogs]
[For use ONLY on dogs]
[Specially Formulated on Dogs and Puppies [Over 7 Weeks [Old][of Age]][7 weeks [of Age] or Older]]
[Specially Formulated for Dogs and Puppies (7 weeks or older)]
[Dogs and Puppies [over 7 weeks [old][of age]][7 weeks [of age] or older]]
[Can be used on puppies [over 7 weeks [old][of age]][7 weeks [of age] or older]]
[The Only Flea Protection You Need For Your Dog[s]!]
[Original Vet Strength]
[Fast Acting] [Long Lasting]
[Convenient]
[Easy application]
[Easy to apply product]
[Easy to Use [Application]]
[One Step Hassle Free Protection!]
[Waterproof]
[Remains effective even after shampooing, swimming, or exposure to [sunlight] [and][or] [rain]]
[Remains effective, even after bathing, water immersion, or exposure to [sunlight] [and][or] [rain]]
[Once a month treatment]
[Apply once every [4 weeks] [month] [30 days]!]
[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]
[For year-round protection, apply [Brand Name][this product] monthly]
[Best if used year round!]
[X Applications] [4 Week Supply] [1 Month Supply]
[One Application] [8 Week Supply] [2 Month Supply]
[Two Applications] [12 Week Supply] [3 Month Supply]

Sergeant's® Master Label

19 December 2014

Version 14.1

EPA Reg. No. 2517-NEW

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Page 5 of 11

[Three Applications] [16 Week Supply] [4 Month Supply]
[Four Applications] [20 Week Supply] [5 Month Supply]
[Five Applications] [24 Week Supply] [6 Month Supply]
[Six Applications] [48 Week Supply] [12 Month Supply]
[9 Applications] [52 Week Supply] [24 Month Supply]
[12 Applications] [104 Week Supply]
[24 Applications]
[[for] Small Dog[s] [[3.5][3½] [to][–] 10 lbs.]]
[[for] Medium Dog[s] [11 [to][–] 20 lbs.]]
[[for] Large Dog[s] [21[to][–] 55 lbs.]]
[[for] Extra Large Dog[s] [Over 55 lbs.]]
[Direct to skin [tube][vial][applicator][pipette]]
[Easy to Use] [tube][vial][applicator][pipette]
[Clean cut [open] [tube][vial][applicator][pipette]]
[No-mess [open] [tube][vial][applicator][pipette]]
[Clip-tip design [tube][vial][applicator][pipette][!]]

ACTIVE INGREDIENT:

Imidacloprid.....9.10%

OTHER INGREDIENTS:90.90%

[TOTAL 100.00%]

KEEP OUT OF REACH OF CHILDREN WARNING

[See [Back][or][Side][Label[s][Panel[s]] for Additional Precautionary Statements]

NET CONTENT: X fl oz [Y – X fl oz applicators]

[0.014 fl oz (0.4 mL) [tubes][vials][applicators][pipettes]]

[0.034 fl oz (1.0 mL) [tubes][vials][applicators][pipettes]]

[0.085 fl oz (2.5 mL) [tubes][vials][applicators][pipettes]]

[0.135 fl oz (4.0 mL) [tubes][vials][applicators][pipettes]]

{END – FRONT PANEL}

BACK PANEL/SIDE PANEL OR INSERT

**Dogs Squeeze On
Imidacloprid**

[The active ingredient in [Brand name][this product] is [imidacloprid,] formulated for fast acting
[and long lasting] control of fleas on dogs.] [[Brand Name][This product] kills fleas within 12
hours and prevents further flea infestations for [up to] [[4][four]weeks][[1][one] month][30
days].]

**READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON DOGS AND PUPPIES 7 WEEKS OF AGE OR OLDER.**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. WARNING. Causes substantial but temporary eye injury. Do not
get in eyes or on clothing. Harmful if swallowed. Avoid contact with skin. Wash hands
thoroughly with soap and warm water after handling.

Sergeant's® Master Label

19 December 2014

Version 14.1

EPA Reg. No. 2517-NEW

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Page 6 of 11

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities, while rare, may occur after using ANY pesticide product for dogs. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing dogs.

FIRST AID	
If In Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If Swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on Skin or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on animals other than dogs. Do not allow your dog to ingest this product. Do not use on puppies under 7 weeks of age or less than [[3.5][3½]] [11] [21] [55] lbs. Use entire contents of [tube][vial][applicator][pipette] on each dog. [Do not split one [tube][vial][applicator][pipette] between dogs.] Do not use multiple [tube][vial][applicator][pipette]s on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.

Side Effects: Monitor your dog after application. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your dog and continue to monitor your dog for the next 24 hours.

Sergeant's® Master Label

19 December 2014

Version 14.1

EPA Reg. No. 2517-NEW

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Page 7 of 11

[1.5 cm x 1.5 cm on final or as indicated]



DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. Contact your veterinarian if applied to a cat or ingested by a cat.

{OUTER PACKAGING}

How to Open: Remove product [tube[s]][vial[s]][applicator[s]][pipette[s]] from the package. [Separate one [tube][vial][applicator][pipette] from the others.] Hold the [tube][vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the lines.

How to Apply: Invert [tube][vial][applicator][pipette] over dog and use open end to part dog's hair. Squeeze [tube][vial][applicator][pipette] firmly to apply all of the solution to the dog's skin, as directed below. Do not apply more often than once every [30 days][4 weeks][month].

{For cartons containing 0.4 mL (0.014 fl oz) applicator tubes}

Only For Dogs Weighing [3.5][3½] [-][to] 10 lbs. [Do not apply to dogs weighing less than [3.5][3½] lbs. [including small dogs and puppies, only 7 weeks or older]] Apply one [tube][vial][applicator][pipette] 0.4 mL (0.014 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail] [as a spot [on][to] the dog's back between the shoulder blades][as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades.][This allows for a more direct application to the skin.]

{For cartons containing 1.0 mL (0.034 fl oz) applicator tube}

Only For Dogs Weighing 11 [-][to] 20 lbs. [Do not apply to dogs weighing less than 11 lbs.] Apply one [tube][vial][applicator][pipette] 1.0 mL (0.034 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail] [as a spot [on][to] the dog's back between the shoulder blades][as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades.][This allows for a more direct application to the skin.]

{For cartons containing 2.5 mL (0.085 fl oz) applicator tube}

Only For Dogs Weighing 21 [-][to] 55 lbs. [Do not apply to dogs weighing less than 21 lbs.] Apply one [tube][vial][applicator][pipette] 2.5 mL (0.085 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail] [as a spot [on][to] the dog's back between the shoulder blades][as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades.][This allows for a more direct application to the skin.]

{For cartons containing 4.0 mL (0.135 fl oz) applicator tube}

Only For Dogs Weighing 55 lbs. or greater. [Do not apply to dogs weighing less than 55 lbs.] [Do not use two [tube][vial][applicator][pipette]s on dogs greater than 55 lbs.] Apply one [tube][vial][applicator][pipette] 4.0 mL (0.135 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail] [as a spot [on][to] the dog's back between the shoulder blades][as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades.][This allows for a more direct application to the skin.]

Sergeant's® Master Label

19 December 2014

Version 14.1

EPA Reg. No. 2517-NEW

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Page 8 of 11

FREQUENCY OF APPLICATION

[Use [Brand Name][this product] monthly for control of flea[s] [infestations].] [[Studies show that] [Brand Name][This product] kills fleas within 12 hours of application and [lasts][protects] [for [up to] [[four][4] weeks][30 days][one month].] [[Brand Name][This product] kills reinfesting fleas within [2][two] hours and prevents further infestations of fleas [for [up to] [[four][4] weeks][30 days][one month]].] [If your dog is at high risk for flea reinfestation [, or in a highly infested environment], apply monthly.] [Apply monthly for optimal flea control.] [[Brand Name][This product] is waterproof and remains effective, even after bathing, swimming, or exposure to sunlight [and][or] [rain].] [Allow treated area to dry thoroughly.] [Do not reapply for [4 weeks][30 days].]

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove [tube][vial][applicator][pipette] from the pack until ready to use. Store only in original container in a cool [(below 77°F/[25°C])], dry area inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: **If empty:** Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's][SENTRY] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

[Satisfaction Guaranteed][If you are not satisfied, we will make it right with a replacement or refund.]

In Case of Emergency, call: 1-800-781-4738

Non-Emergency, call: 1-800-224-PETS (7387)

[Coupon(s) inside or on outside of box]

[Made in USA]

[Distributed by:] [Manufactured by:]

Sergeant's Pet Care Products, Inc.

Omaha, NE 68138-3710

EPA Reg. No. 2517-NEW

EPA Est. No. XXXXX-XX-XX

[BAR CODE AREA]

{END - BACK/SIDE PANEL}

{START - OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE}

Sergeant's® Master Label

19 December 2014

Version 14.1

EPA Reg. No. 2517-NEW

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Page 9 of 11

[How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.]

[Clip. Part. Squeeze.]

Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting proven flea protection where it needs to be.]

[Application Instructions][Directions for Use]

How to Open:

1. Remove product [tube[s]][vial[s]][applicator[s]][pipette[s]] from the package.
2. [Separate one [tube][vial][applicator][pipette] from the others.] Hold the [tube][vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Invert [tube][vial][applicator][pipette] over dog and use open end to part dog's hair.
2. Squeeze [tube][vial][applicator][pipette] firmly to apply all of the solution [on] [to] the dog's skin [as a spot to the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

[Look at the Label (Look at the Label icon) [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist]

- [1] Read the label completely and follow directions
- [2] Weigh your dog
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after [treatment] [application] to avoid chance of ingestion
- [6] Do NOT split [tube][vial][applicator][pipette] between dogs[and use the ENTIRE [tube][vial][applicator][pipette] contents]

[Brand Name][This product]

[Monthly reminder card]

[1][2][3][4][5][6][12][24][Month [Treatment] [Application] Tracker][Carecard]

[For year-round protection, apply [Brand Name][this product] monthly.]

[Dog's Name (Empty blank for owner to fill in name)]

[Dog's Weight (Empty blank for owner to fill in name)]

[First][1st][Second][2nd][Third][3rd][Fourth][4th][Fifth][5th][Sixth][6th][Seventh][7th][Eighth][8th][Ninth][9th][Tenth][10th][Eleventh][11th][Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)]

[Application Date][Date of Application]

[Calendar stickers with Brand Name]

[Place stickers on your calendar as a reminder to reapply [Brand Name][this product] [in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Place sticker on your calendar [or refrigerator] to remind yourself to apply [Brand Name][this product] to your dog]

[33% More Free]

[Bonus Size]

Sergeant's® Master Label

19 December 2014

Version 14.1

EPA Reg. No. 2517-NEW

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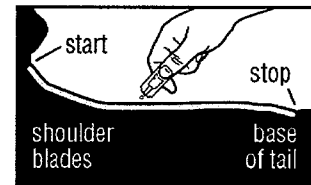
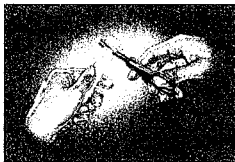
Page 10 of 11

[Buy 3 get 1 free]

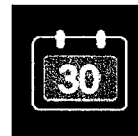
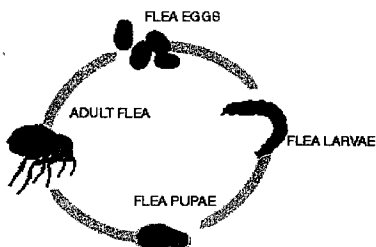
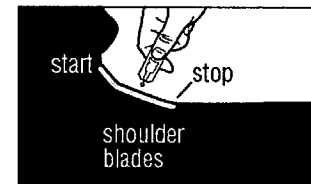
[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [Brand Name][this product]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

[Each optional graphic below may or may not appear anywhere on the finished label]

	Adult Flea	
	Fleas	
	Flea Larvae	



DO NOT USE
ON CATS



MADE IN THE
USA

MADE IN THE
USA
WITH GLOBAL MATERIALS

[Flea life cycle diagram] [Flea Life Cycle]

{END – OPTIONAL INSERT OR PACKAGE COPY}

Sergeant's[®] Master Label

19 December 2014

Version 14.1

EPA Reg. No. 2517-NEW

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Page 11 of 11

TUBE/VIAL LABEL

**Dogs Squeeze On
Imidacloprid**

{Front Label}

{Back Label}

<p>[Brand Name (for dogs)] [X-Y] lbs. ≥7 wks Imidacloprid 9.10% 0.014 fl oz (or) 0.034 fl oz (or) 0.085 fl oz (or) 0.135 fl oz {label code}</p>	<p> KEEP OUT OF REACH OF CHILDREN WARNING: Read directions and precautions before using. Use scissors to open. EPA REG. No. 2517-XXX {label code}</p>
----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

{EPA REG No may be on either the front or back label}

{END – TUBE/VIAL LABEL}

